UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, and COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v. 20 CV 706 (DLC)

MARTIN SHKRELI, et al.,

Defendants.

New York, N.Y.
December 15, 2021
9:30 a.m.

Before:

HON. DENISE COTE,
District Judge

APPEARANCES

FEDERAL TRADE COMMISSION
BY: MARKUS H. MEIER
MARIN HANEBERG
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SARAH FEHM STEWART
SEAN McCONNELL
J. MANLY PARKS

(Trial resumed; in open court)

MR. MEIER: Markus Meier, on behalf of the Federal Trade Commission.

THE DEPUTY CLERK: Please state your names for the record.

THE COURT: No, that's just fine. We did that the first day of trial. Thank you very much, Mr. Whertvine.

Excuse me one second.

(Pause)

THE COURT: I received a letter from counsel for CareMark dated December 14, and I believe counsel have had an opportunity to discuss this with each other. It makes a request for redaction of passages from the deposition that appear at pages 103 to 105.

Can someone give me a report from the parties?

MS. STEWART: Good morning, your Honor. Sarah Stewart, on behalf of the defendant.

We're agreeable to the proposed redactions.

MR. MEIER: Your Honor, on behalf of the FTC, I think we were already okay with it, so I think it's okay.

THE COURT: I've reviewed it. It's limited in request. Most of the requests made by CareMark were denied at a conference on Tuesday. The limited nature here, I don't think, is terribly critical to the issues before me and has some concern about competitive advantages, and, therefore, I

approve the request to redact.

With that, I think we're ready to resume examination of the witness. Am I right, or, counsel, do you have other issues?

MR. MEIER: Yes, your Honor, if I may. Markus Meier, on behalf of the Federal Trade Commission.

We do have just a couple of administrative matters, if we can take those up first, your Honor?

THE COURT: Sure.

MR. MEIER: First, I'd like to introduce the paralegal that will be working with us today and operating the technology — hopefully, we will have more success with the technology — that is Phoebe Flint, your Honor.

And next, I wanted to introduce a number of exhibits that we've already discussed with the defendants. It's my understanding that there should be no objections to any of these, but I did want to take them one by one.

The first one is Government Exhibit 9053.

Your Honor, Government Exhibit 9053 is the revised designations of the transcript of a witness named Desai from ASD, and, again, we've indicated on the front cover the changes from the original that we submitted back in October, and as with the other designations, they are color-coded in the same manner as we've been submitting to date.

THE COURT: Any objections to receipt of 9053 other

than objections on which I've already ruled?

MR. POLLACK: No, your Honor.

THE COURT: Thank you.

9053 is received.

(Government's Exhibit 9053 received in evidence)

MR. MEIER: The next one, your Honor, is Government Exhibit 9054. These are the designations of the transcript of Mr. Shah from an Indian company called Aadivignesh — I'm sorry, I don't know how to pronounce that properly, but it's spelled A-a-d-i-v-i-g-n-e-s-h. In this particular one, there are no changes from the version that was submitted as part of the pretrial package in October.

THE COURT: Any objections other than those I've already ruled on?

MR. POLLACK: No, your Honor.

THE COURT: 9054 is received.

(Government's Exhibit 9054 received in evidence)

MR. MEIER: The next one, your Honor, is Government Exhibit 9055. It's the deposition --

THE COURT: Excuse me.

If you could be seated, sir, at the back. Thank you.

MR. MEIER: Your Honor, Government Exhibit 9055, it's the designations of Marco Polizzi from a company called Oakrum and there are no changes from the designations submitted back in October.

THE COURT: Any objections other than those I've already ruled on to 9055?

MR. POLLACK: No, your Honor.

THE COURT: 9055 is received.

(Government's Exhibit 9055 received in evidence)

MR. MEIER: The next one, your Honor, is Government Exhibit 9056 -- let me put my reading glasses on just to confirm -- yes, 9056, and this is the designations of the deposition of Paula Raese, R-a-e-s-e, from Mylan, M-y-l-a-n, and there are no changes from what we submitted back in October.

THE COURT: Any objection to the receipt of 9056 other than objections on which I've already ruled?

MR. POLLACK: No, your Honor.

THE COURT: Thank you.

Received.

(Government's Exhibit 9056 received in evidence)

MR. MEIER: The last one for this morning, your Honor, is Government Exhibit 9057. It's the deposition designations of John Vande Waa, capital V-a-n-d-e, separate word W-A-A, from a company called USA Health, and there are no changes from the versions submitted pretrial in October.

THE COURT: Any objections to the receipt of 9057 other than what objections may have been made and on which I've already ruled?

MR. POLLACK: No, your Honor.

THE COURT: 9057 is received.

(Government's Exhibit 9057 received in evidence)

MR. MEIER: Thank you, your Honor.

My colleague from New York A.G.'s Office, Ms. Hoffman, also has an administrative matter she'd like to raise, and then we'll call the next witness.

MS. HOFFMAN: Good morning, your Honor. Eleanor Hoffman, from New York.

Your Honor may recall last Friday, I indicated that we may need briefing on the impact of the defendant's new affirmative defense. I since discussed with the defendant, and I think we're in agreement, that no briefing is necessary now, and may not be. So we are not going to be submitting briefs, if that's acceptable to your Honor, before the 21st.

THE COURT: It's what?

MS. HOFFMAN: We will not be submitting briefs, if that's acceptable to your Honor, before the 21st.

THE COURT: Great. Good.

Let me just ask plaintiffs' counsel, Mr. Meier: I noticed you made a limited offer of exhibits yesterday, some individual exhibits with a witness, but others with a document that listed various exhibit numbers.

What is the procedure that you're following? Are you planning to withdraw most of your exhibits, or are you planning

to offer most of them, but in tranches?

MR. MEIER: We are planning to offer most of them, but in tranches, and we're working through those details every night and over the weekend and making sure -- our hope is to initially put in the ones where we don't have any objections, where we can get agreement. And I probably will be actually doing one of those this afternoon before the day is over, and we're working through -- I think we probably have two or three or four already that are going back and forth. So that would be the plan, your Honor, we will move them in through -- those that aren't used with a witness in the moment here in Court, we will seek to move in as many of those as possible that we can get agreement on, and those we can't, we'll have to have some discussion with your Honor about.

THE COURT: Great. Thanks for giving me that heads-up.

Is this the time for the witness to retake the stand?

MR. MEIER: Yes, your Honor. We would recall Mr. Bruno, and, again, my colleague, Neal Perlman, for the FTC, will handle this witness, but I think the defendants want to finish their examination.

THE COURT: Mr. Bruno, if you could take the stand.

Mr. Bruno, I remind you, you're still under oath.

Counsel.

MR. PARKS: Thank you, your Honor.

And good morning, Mr. Bruno.

THE WITNESS: Good morning.

MR. PARKS: As a first matter, your Honor, yesterday, at the end of the day, I had asked the witness a question, and I had referred to his direct testimony. I indicated at paragraph 23, this is a question regarding the requirements and capacity reservation provisions in GSK's supply agreement with Fukuzyu and whether they require Fukuzyu to ensure that it meets GSK's requirements first. We determined, from a quick look yesterday, that my citation to paragraph 23 of that direct testimony was incorrect, and I discovered shortly after the session yesterday, that it was page 23, not paragraph 23.

Perhaps we can put that up, Justin.

It is paragraph 71, it begins on page 22, but the relevant language can be found at the top of page 23 of the direct testimony. So I just wanted to correct that reference for the record.

With that, your Honor, I will proceed.

JAMES BRUNO,

CROSS-EXAMINATION CONTINUED

BY MR. PARKS:

Q. Sir, in your direct testimony, you state that, "Where the API supplier has already filed a DMF with the FDA, it is unusual for the supplier to agree to exclusivity," and that's in your direct testimony at paragraph 77. I would like to

focus, sir, on the word "unusual" there.

You were saying that based on your personal experience, that would be unusual, correct?

A. That's correct.

Q. Earlier, you said that over your career — and earlier, I mean yesterday in your testimony — you said that over your career, you've been involved in some capacity with 100 -- approximately 100 pharmaceutical manufacturing contracts, correct?

A. Correct.

Q. And of those 100 contracts, you said you were closely involved in approximately 40, correct?

A. Correct.

Q. Not one of those 100 pharmaceutical manufacturing agreements that you were involved in some capacity with over your career related to pyrimethamine, correct?

A. That's correct.

Q. And you told us that you did not do any formal study regarding the frequency that different deal terms appear in API supply agreements, correct?

A. That's correct.

Q. You also told us that you did not review, and are not aware of, formal -- any formal survey analyzing the frequency with which different terms or conditions appear in API supply agreements, correct?

A. That's correct.
Q. So because you did not conduct any industrywide analysis, you really can't say if an agreement to exclusivity under these circumstances is actually unusual in the industry, can you?
A. My comment was that based on my experience with the contracts that I've worked on, and that I've been involved with, also, with my contacts with other companies, discussing with CMOs and pharmaceutical companies, that it's unusual.
Q. So to my question, you can't say whether that's actually unusual in the industry because you didn't study the industry for your analysis, did you?
A. I did not do a formal study. I did it with companies that I had been working with over the 40-some years.
Q. Now, I'd like to turn to Vyera's contract with RL Fine.

In your direct testimony affidavit, you stated that the contract Vyera entered into with RL Fine was "not a legitimate backup API supply agreement," and that's direct testimony, that's the heading immediately before paragraph 78.

A core basis for that conclusion was that RL Fine was not actually able to serve as a backup supplier for pyrimethamine to Vyera at the time of the agreement, correct?
A. That's correct.
Q. Even though RL Fine had not taken steps toward filing a DMF for pyrimethamine API, it was still the next best supply option for pyrimethamine API after Fukuzyu at that time, wasn't it?

A. That's correct.
Q. You don't have an issue, sir, do you, with the fact that Vyera identified RL Fine as a possible alternate supplier of pyrimethamine, do you?
A. As I said in my statement, they were the second best option at the time.
Q. So you don't have an issue with Vyera having identified RL Fine as a potential API supplier, right?
A. That's correct.
Q. And that was the actual conclusion that you reach in your direct testimony, that after Fukuzyu, the next best pyrimethamine API supply option was RL Fine, right?
A. That's correct.
Q. You also take issue with the amount of due diligence done by Vyera before identifying RL Fine.

My question for you is this, sir: Regardless of the amount of due diligence Vyera did, it ended up identifying the exact same next best option for pyrimethamine API supply that you identified in your analysis, didn't it?
A. In the initial phase of it, yes.
Q. Now, you said in your direct testimony affidavit that various aspects of the supply agreement between RL Fine and Vyera were, to use your word, atypical of backup supply API supply agreements and, again, using your language, inconsistent with industry practice regarding such agreements, and that's in

your direct testimony at paragraphs 88 and 90.

You are basing those conclusions, again, on your own personal experience and not any study or analysis of the pharmaceutical industry; isn't that right?

A. I did not do a formal study of the industry, as you said.

Q. And so your conclusions about this agreement being atypical and inconsistent with industry practices are actually limited to your own personal observation in your experience and not any study of the industry, correct?

A. It is not based on a formal study.

Q. And they are limited to your personal experience, right?

A. Yes, which is 40 years in the industry.

Q. Well, we'll talk about that.

The reference point, over 40 years, is 100 agreements with which you have had some agreement -- I'm sorry, some involvement and 40 agreements with which you were closely involved, right?

A. You have to define when I said the 40, as I said yesterday, 40 of them, I was the lead person. The other ones, I took care of just a portion of it, which would have been the CMC section.

Q. But your reference point for these opinions is those 100 agreements and those 40 agreements on which you were the lead of the 100, correct?

A. Not exactly.

And, again, I work with a lot of CMOs, and I work with

a lot of pharmaceutical companies. Discussing what the terms and conditions of a contract is part of our discussions, and even before we get to a supply agreement, we are discussing those type of things. We may not have gotten to the supply agreement, but they're not done in a vacuum, and we're not waiting to the very end to do it.

So my conclusions are based on that experience and my discussions with hundreds of CMOs and multiple numbers of pharmaceutical groups.

Q. Yesterday, sir, you told us that of the 40 agreements that you were closely involved in, approximately 20 were backup supply agreements, correct?

A. No, that's not what I said.

Q. You didn't say that?

A. I said 20 were second suppliers.

Q. Secondary supply agreements?

A. Correct.

Q. Were any backup supply agreements?

A. There were no backup suppliers in there.

Q. So you have had no experience with backup supply agreements?

A. Not on -- I have not done a formal backup supply agreement.

Q. Okay.

Speaking of backup agreements, generally, you were retained by the FTC as an expert witness in a matter prior to

this case, weren't you?
A. Correct.
Q. That was the AndroGel case, wasn't it?
A. Yes.
Q. In that case, your opinions related, in part, to a backup manufacturing agreement, didn't it?
A. Yes.
Q. And the court in that case granted a motion to preclude you from testifying about part of your opinion, didn't it?
A. I'm not aware of an official judgment on that, on what they precluded.
Q. You're aware that a judge ruled that you couldn't testify to part of your statement in that case, aren't you?
A. I don't recall being advised that I couldn't testify in court. I gave my deposition, and that's as far as the case went.
Q. Sir, yesterday, you testified that you were deposed in this case on July 29, 2021, and I'd like to take a look at your deposition from July 29, 2021, on page 81, lines 15 through 25.
THE COURT: Have you laid a foundation for this testimony, counsel?
MR. PARKS: I'm sorry?
THE COURT: Have you laid a foundation for examining with respect to this testimony?
MR. PARKS: This testimony -- this is his deposition

in this case.

THE COURT: So has he testified inconsistently with his deposition?

MR. PARKS: I believe he has, yes.

THE COURT: Oh, okay. Thank you.

MR. PARKS: Yes.

BY MR. PARKS:

Q. And if we look on page 81, at lines 15 through 25, you were asked a question at line 15: "In any of these five cases that you identify in paragraph 19, were you retained by any of the plaintiffs, who are, in this case, the governmental entities, or the plaintiffs in this case?"

And your answer, at line 20, was: "I was retained by the FTC."

And then the question to you was: "Which one was that?"

And your answer was: "I think that was AndroGel."

And the question to you was: "That was the one where part of your testimony was excluded?"

And your answer was: "I think so. I would have to check."

Right?

MR. PERLMAN: Objection, your Honor. Counsel is just reading this deposition into the record. I don't think this is proper impeachment. Mr. Bruno testified that he was retained

by the FTC in AndroGel, so I don't see an inconsistency.

THE COURT: Overruled.

BY MR. PARKS:

Q. Sir, you testified in your deposition that you recognized that part of your opinion was excluded in AndroGel, didn't you?

A. If that's what I said, then I forgot that that was the case, and as I said in that, I think that was the one that I didn't recall at this point.

Q. Thank you.

You recall -- has that testimony from your testimony refreshed your recollection on that point?

A. I would have to read more of it to see what the discussion was about, to why I was talking about that, but, to be honest with you, that was done a very long time ago, and I don't remember the exact details. I haven't reviewed that case in years.

Q. Sir, the court in the AndroGel case ruled that because you failed to engage in any quantitative valuation of the backup manufacturing agreement at issue in that case, you were not permitted to offer testimony about a specific monetary valuation for that agreement; isn't that right?

A. I think I understand where you're going, and I think I'm -- I think this is what I will recall. I don't recall all the exact details, but I think I know what this is about.

Q. Is that consistent with your general recollection of the

court's ruling in that case?

MR. PERLMAN: Objection; relevance, your Honor.

THE COURT: Sustained.

BY MR. PARKS:

Q. Sir, just like in AndroGel, where you offered an opinion without doing any substantive valuation analysis that the backup manufacturing agreement there had no value, here, you are offering the opinion that certain provisions in the supply agreements to which Vyera was a party were atypical and inconsistent with industry practice without any substantive industry analysis either, aren't you?

MR. PERLMAN: Objection; relevance and argumentative.

THE COURT: Argumentative, form. Sustained.

MR. PARKS: I have no further questions for the witness at this time. Thank you.

THE COURT: Thank you.

REDIRECT EXAMINATION

BY MR. PERLMAN:

Q. Good afternoon, Mr. Bruno.

A. Good morning.

Q. Again, this is Neal Perlman, and I represent the Federal Trade Commission.

Mr. Bruno, I'd like to just start with the second to last topic that Mr. Parks discussed with you.

Do you recall discussing, just now, the backup supply

agreement between RL Fine and Vyera?
A. Yes, I do.
Q. In your professional experience, is Vyera's contract with RL Fine consistent with a typical backup supply agreement?
A. I do not consider it to be consistent with a typical backup supply agreement.
Q. Why not?
A. I think the main point is that RL Fine was not listed in any of the FDA documents. Since it wasn't added to the AND or the NDA for Daraprim, that from a regulatory point of view, they could not use that API in their formulation in their process. So inside the contract, there was no relevance to getting that approval, and whether it's a backup supplier or a second supplier or a primary supplier, most of the contracts -- almost all of the contracts that I work on, there's some trigger in there that says that you have to be approved, you have to be able to submit your documents.

All that has to be done, and RL Fine did not, and was never approved, as a supplier. So as a backup supplier, as a second supplier, even a primary supplier, their material could not be used in any of the Daraprim that was sold in the U.S. market.

Q. Why does it matter whether a supplier is approved for use by the FDA if it's a backup supplier?
A. The whole premise of a backup supplier, as it's been

defined, is that their job is to be available in case there is a problem and there's some interruption in the delivery of the materials. If you're not approved, then if there is an interruption, that material has to be put into a process, which gathers information, both on the API and the dosage, tests have to be done, it has to be submitted to the FDA, and the FDA has to review that information.

The FDA review alone could take 18 to 24 months. So if there is a supply interruption, then I could be without product for 18 to 24 months. Considering, in Vyera's case, this was their number one product, it's economically what they lived and died on. So, if they're not getting that income, that company could be out of business in that time period, on just the FDA, not even on the part at the beginning where it takes to get all that information and the work required.

Q. In your view, does Vyera's contract with RL Fine mitigate supply risk?

A. I don't think it mitigates supply risk at all.

Q. Why not?

A. Again, because of the issues associated with the FDA. Also, there are better ways to mitigate the risk, which would have been less expensive for them. Again, they could have bought inventory. Also, if you look at the contract, there was no, again, part of the trigger. They were getting fees even though they weren't supplying, even though they couldn't

supply. That's not usual in a contract. The contracts that I've worked on and I've been involved with, as I said, we have milestones. When the product is approved, you get a milestone payment; when you get a submission, you get a milestone payment. This gives an incentive to the manufacturer to actually get these things done.

RL Fine didn't do that. Vyera never purchased products to do that. There was no interaction between the two to move this thing forward, and, therefore, it didn't mitigate the risk of a supply interruption.

Q. I'd like to switch gears a little bit here and turn us to the discussion that you had with Mr. Parks about bargaining leverage.

Let me just ask: Do you recall that discussion with Mr. Parks yesterday?

A. Yes.

Q. In your experience, do API suppliers prefer to include forecasting provisions in their supply contracts with pharmaceutical companies?

A. Yes, they do.

Q. Why is that?

A. It gives them an opportunity for planning. You have to look at the facility. Most CMOs that are there, they look at capacity, and when their capacity reaches a certain amount, then they'll invest. So forecasting allows them to do their

planning, it gives them an opportunity to see what products they can do, they can't do, and, also, it gives them an opportunity to look at when they're going to implement the investments.

Often these investments take two years to get all the permits, to bring in the equipment, to qualify, to certify, and get things ready, so it's not something that you just do overnight. Forecasting is very important for all of that type of thing.

Q. Now, in your experience, do API suppliers prefer to have exclusive provisions in their contracts with pharmaceutical companies?

A. The exclusive parts of the contract are a different sense. It's used often in the very beginning of the project, when it's in its clinical development. For one, you don't know if the project is going to succeed, and, also, there's a cost of bringing on a second supplier, there's a cost of bringing on a backup supplier.

The smaller companies, they don't have that wherewithal, both financially or by the people themselves, so they may look to get an exclusive arrangement that will get them through all of their development period, that will get them potentially into launch, and once they get there, they'll start looking at second suppliers. Once they get the product launched, you know you have a product, you know you have an

income, you can afford to bring on all those costs. And some of those costs could run a million dollars.

THE COURT: So I think the question you were asked was from the perspective of the supplier, not the buyer.

Can you just answer from the perspective of the buyer?

THE WITNESS: No. I thought I was talking about the supplier because of that, but I did bring in the buyer because the two are related.

MR. PERLMAN: Your Honor, I can try to ask a clarifying question.

BY MR. PERLMAN:

Q. When an API supplier agrees to exclusively sell to one pharmaceutical company -- let me rephrase that.

When there's an exclusive contract between -- let me rephrase that again.

Does an API supplier prefer to sell to one pharmaceutical company or multiple pharmaceutical companies?

A. A CMO for a product that they develop, they would prefer to supply as many companies as they could. It gives them more volume and, therefore, better economics.

Q. Okay.

So, again, turning to the discussion with Mr. Parks about bargaining leverage, in your understanding and your knowledge of the industry, does an API -- do API suppliers prefer to have a forecasting provision or an exclusivity

provision in their contracts?
A. The forecasting provision would be much more important because it goes back to planning.
Q. From the perspective of -- shifting gears, and from the perspective of a pharmaceutical company, does it require more leverage for a pharmaceutical company to secure a forecasting provision from a CMO or an exclusivity provision?
A. I think the forecasting would be more important, because, again, you can --
THE COURT: More important to whom?
THE WITNESS: To the pharmaceutical company — thank you — because it allows both parties to understand what they're going to need for capacity in the future. So the forecasting becomes extremely important in that respect.
BY MR. PERLMAN:
Q. Understood. I'm asking just a slightly different question, Mr. Bruno.
So, thinking about the pharmaceutical company's perspective, and you're thinking about the bargaining dynamics between a pharmaceutical company and an API supplier, would it require more bargaining leverage from the pharmaceutical company to secure an exclusivity provision or a forecasting provision from the API supplier?
A. Based on my experience, it would still be -- the forecasting would be -- would give them more bargaining power

because it would give the CMO an understanding of when they would have to make -- when their income would be generated, so they would have more of a leverage in order to talk in that respect.

Q. I'd like to turn to paragraph 71 of your affidavit. We don't need to put it up on the screen, but we spent a lot of time talking about the relationship yesterday between GSK's contract with Fukuzyu and Vyera's contract with Fukuzyu.

Do you recall that testimony?

A. Yes.

Q. Mr. Bruno, could you remind the Court what the scope of the exclusivity provision in Vyera's contract with Fukuzyu is?

A. Basically, they were going to control the U.S. market for human health in their exclusivity. So, Vyera would be restricted from selling any product into the United States for human health. That was the primary part of, I would say, their contract in that regards.

Q. You just said "Vyera." Did you mean Fukuzyu?

A. I'm sorry. Fukuzyu.

Q. Just to be clear, under the exclusivity provision, could Fukuzyu sell pyrimethamine API outside of North America?

A. That's correct.

Q. To customers other than Vyera?

A. And outside of the human health, as well.

Q. Inside the United States?

A. Correct.

Q. I'd like to pose a hypothetical to you, Mr. Bruno. If demand for pyrimethamine API outside the United States rose, is there anything in the Fukuzyu supply contract with Vyera that would ensure that Fukuzyu would continue to supply Vyera?

MR. PARKS: I am going to object. It's not in the report, it's not in his direct testimony, there's no expert opinion on this, and so I don't think it's proper.

THE COURT: Overruled.

THE WITNESS: Would you repeat it again, please?

BY MR. PERLMAN:

Q. Sure.

If demand for pyrimethamine API outside the United States rose, is there anything in Vyera's supply contract with Fukuzyu that would ensure that Fukuzyu would continue to supply Vyera?

A. I saw nothing in the contract that would guarantee that as the volumes rose, that Vyera would be guaranteed deliveries of the material.

Q. Mr. Bruno, in your review of the contract, what happens when Vyera sends a purchase order to Fukuzyu?

A. According to the contract, Fukuzyu has ten days to respond to the contract.

Q. To the purchase order?

A. To the purchase order.

Q. Can Fukuzyu reject the purchase order?
A. I saw nothing in the contract that said that Fukuzyu had to accept the contract -- accept the purchase order, and if they didn't do it within the ten-day period, they could, in effect, reject it.
Q. Okay. Here's my last set of questions. We're going to shift gears slightly.

I think at the beginning of your testimony yesterday, you discussed with Mr. Parks a number of companies that you had worked for before and whether those companies had exclusive contracts. So I'd like to ask you a few questions about that.

Just to start, Mr. Bruno, why do pharmaceutical companies typically seek exclusive API supply contracts?
A. We're talking about the pharmaceutical companies?
Q. That's right.
A. So what happens when you're a company, and you're trying to get an exclusivity, you're looking at your market, and so the limit -- the more you can limit that API going to other people, the longer you can delay the potential of the product going into the marketplace and, in effect, competing with you.
Q. Are there any other reasons?
A. You are also looking to assure that you get supply materials so you can maintain your market share. So these are the kinds of things that you're trying to do. Once you've launched a product, you don't want to be without. As you go

forward, you want to make sure that you can get all of your regulatory parts.

So all those aspects can get tied in, and you're also making investments, so you're spending money, and you want to make sure that you can get a return on all the money you spent in order to get that product launched on the market.

Q. So I'd like to just make sure we're clear about something.

When you said that companies prefer to have exclusive supply contracts, are you drawing a distinction between the supply contract and the exclusivity provision itself?

A. I --

THE COURT: Counsel, I'm a little confused by the reference to company. If you could identify if you're talking about the purchaser, the pharmaceutical company purchasing the API, or the manufacturer supplying it, I could better understand your question.

MR. PERLMAN: Sure. And I will try to rephrase it, as well.

BY MR. PERLMAN:

Q. Let me ask you this question, Mr. Bruno: Why do pharmaceutical companies typically seek exclusivity provisions in their supply contracts?

A. The exclusivity will guarantee them a supply of material, it will limit the amount of API that is available in the marketplace, so it will allow them to maintain market share,

and because they're covering an investment, they need to make sure that they can maintain that income in order to cover the investment, which has occurred -- which could be several years.

Q. How does an exclusivity provision guarantee supply?

A. It doesn't guarantee supply from a manufacturing point of view because unless you put something in the contract, and it's not just an exclusive provision that says that I will make the material, I will have either inventory available, I will have capacity available, so those are other provisions within the contract that give you that guarantee of the supply. The exclusivity, I don't see that in the contracts I've done, have not limited the ability for you not to get material — excuse the double negative — but you need other stipulations within the terms of the contracts. The exclusivity provision does not do it.

Q. Do exclusivity provisions — and I want to stay focused on the exclusivity provision itself — in API supply contracts ensure high quality for the pharmaceutical company?

A. Again, the exclusivity doesn't do that. You're -- within the context of the contracts, there's normally a provision that says something about you'll maintain GMP standards, you'll have specifications. Those are what dictates your quality and also your quality agreement, not the exclusive provision.

Q. Okay.

So I'd like to just wrap up with this question: Do

you recall discussing the exclusivity provision in the Fukuzyu supply agreement with Mr. Parks?

A. Yes.

Q. Does the exclusivity provision in Vyera's contract with Fukuzyu mitigate supply risk?

A. As I said in my report, it does not mitigate the supply risk because the exclusivity is one piece of it. Also inside that contract, there's nothing that guarantees that they will get their material and that Fukuzyu guarantees the supply of material. There's no provisions for the forecasting, there's no provisions for saying that I'll give you the capacity.

In the Glaxo, the GSK one, those things exist, and it's clear that you know that you're going to be able to get the material, but, again, those are provisions outside of this, I would say, exclusive provision.

MR. PERLMAN: Your Honor, I have no further questions for the witness at this time.

THE COURT: Thank you.

Any recross?

MR. PARKS: Manly Parks, for the defendants.

No, your Honor.

THE COURT: Thank you.

So, there was a line of questions that I found confusing about leverage.

THE WITNESS: Okay.

THE COURT: So let me just see if I can summarize what I thought I understood you to be saying.

Forecasting provisions, suppliers of API like them because they permit them to plan?

THE WITNESS: Correct.

THE COURT: And so if you were a pharmaceutical company seeking to buy, it would be easier for you probably to convince the manufacturer to include, as part of the contract provisions, forecasting?

THE WITNESS: Correct.

THE COURT: But that's linked, from the buyer's point of view, probably, to other provisions that would make sure that orders you placed connected to the forecasting would be fulfilled. And what are those provisions?

THE WITNESS: So what happens on a -- first of all, you can talk about what we refer to as rolling forecasts. And so just -- I'll make up some time frames. So if your contract begins, essentially, say, January 1st, so in the third or fourth quarter of the year before, you would put in what we refer to as rolling forecasts. So we call it rolling because throughout the course of the year, it could be changing, so it's not a fixed number.

So what the supplier will do is they'll talk to the pharmaceutical company. The pharmaceutical company will say, well, we think we're going to need this much material on this

date, and they're planning it around the dosage as well as the API.

So then what will happen is you'll get the forecast, and then you'll order purchase orders against the forecast and say I'll give you a purchase order on January 1st of something, and then that becomes a binding -- and that's the binding piece.

THE COURT: So what is the contract provision linked to that that indicates -- that links the forecast to the binding nature of fulfilling the purchase order?

THE WITNESS: Well, you'll have a forecasting piece, and you'll have a purchasing order piece. And you'll define the purchasing order that the first purchasing order would be put on a certain day and, that will be binding, and then you'll talk about additional purchasing orders throughout the course of the year.

But, also, what you will put in the contract, the forecasting piece, is -- and, again, just to make up a number, I may say I'm going to make 100 kilos, and that's what my forecast is.

(Continued on next page)

THE COURT: Who are you referring to?

THE WITNESS: I'm sorry. The contract manufacturer will be told by the pharmaceutical company that they are going to need a hundred kilos. The contract manufacturer, the CMO, will then put into their budget that they are going to make a hundred kilos. But inside the forecasting piece of the contracts they normally have a provision for going above that number. So as an example --

THE COURT: So it's a minimum order requirement?

THE WITNESS: Not an order. It's a forecast at this point still. They have planned to make 100 kilos, but in their plan --

THE COURT: Who is planning to make a hundred kilos?

THE WITNESS: The contract manufacturer. I'm sorry. I'll try to be more exact. The contract manufacturer has the hundred kilo number. They, the contract manufacturer, will turn around and in their gross planning for the year for all of their products the contract manufacturer will put 100 kilos. But most likely they will put 120 kilos. When I worked for a CMO and I was in charge, we put about a 20 percent because you want to be able to cover that number.

Then once that number is in place, you have your planning. Then the next provision will be the purchase order. Purchase orders will be the binding orders. Normally, in the forecasting piece the company, the pharmaceutical company and

the CMO will be talking throughout the year and they will be discussing their needs and the demand, how they go up and how they go down. They will make adjustments in the forecast. And then the purchase orders will be issued according to that and purchase order is normally the binding piece of it in that respect. It's a constant and continuous conversation between the two parties. Neither one of them is doing this in a vacuum.

THE COURT: But the contract doesn't commit to the state you have described it to us yet that that purchase order must be filled.

THE WITNESS: Normally, in the contract, the first part of the contract talks about a purchase order that must be filled. They guarantee that they will supply the minimum amount, which would be the hundred kilos. They, the CMO, guarantees that they will supply that much based on the forecast.

THE COURT: What's the time lag, or does it depend on the product and the manufacturer, between receipt of the forecast from the customer, the buyer of the API, and the receipt of the purchase order which defines the precise quantity desired at that moment?

THE WITNESS: Normally, you do the forecast the quarter before the contract year starts. So, again, just say you would do it in November if the contract starts January 1.

That's the first piece.

Inside the contract, the first purchase order, there will be a date and that has to be submitted. You may say you must do that in January, February, or March or some time frame.

And that purchase order, depending on what the two have either agreed to or what the discussions are, will either be the orders for the year or it will be the order for the next quarter. If it's an existing product, pyrimethamine was an existing product. I could envision getting a contract that gave me a rolling forecast of, again, a hundred kilos and then getting an order in the first quarter which could have been, I want 50 kilos in January and I want 50 kilos in June, that type of thing. That would be, again, the purchase order and that would be defined in the purchase order in that regards.

THE COURT: What contract provisions protect the buyer of the API that it will actually get from the supplier the API that it needs?

THE WITNESS: In the contract, I normally see it in the purchase order, that that hundred kilos will now be defined as the minimum amount of material that they must buy for that year.

THE COURT: If I provide, pursuant to contract terms, a forecast in the fourth quarter and then I submit a purchase order to you the following year on a schedule we have agreed to, you are required, seller of the API, to provide that amount

of API that I defined in my forecast at a minimum.

THE WITNESS: At a minimum, yes.

THE COURT: Or there is a financial penalty if you do not.

THE WITNESS: There is normally some kind of financial penalty.

What I often see in the contracts, especially if you have a second supplier, because the first supplier normally supplies a larger amount, they normally get a better price. There is a second supplier, smaller amount, they normally have a higher price. The contracts that I have worked on will often define that difference in price. If I don't supply you, then I have to pay -- I, the CMO. I have to pay that or pay some penalty in that respect.

THE COURT: So you testified earlier this morning that once a DMF is filed for a particular API, it's unusual for the manufacturer of the API and the buyer of the API to have an exclusivity provision in their contract.

THE WITNESS: If that API -- if that DMF --

THE COURT: Did I understand your testimony correctly?

THE WITNESS: I think so. But I think there was more to it that may not be correct.

THE COURT: Please explain.

THE WITNESS: So if I have what I refer to as a multioutlet product, what I would say is, those kinds of

products, you want to sell as much as you can. So I, the CMO, would submit a DMF. The DMF would go into a file and the whole world would know that I'm making that product.

THE COURT: Are you saying that the knowledge that you have filed, that you the manufacturer have filed in the DMF is public information.

THE WITNESS: Once you filed, you will get a number from the FDA and that is in a database and it is another database. When I looked at who could do pyrimethamine, I went into two databases. One was the FDA DMF list and the other was a pay service that I support.

THE COURT: A subscription service.

THE WITNESS: A subscription service. That was the Newport. A lot of companies will actually use that almost as an advertisement, so I can show the world I'm making it. If you're a generic house, you are going to call me up and say, I see you're making this. Therefore, can you supply me.

THE COURT: Now the details of the DMF, the manufacturing process, the quality controls, perhaps the ingredients even, those are not public when you file the DMF.

THE WITNESS: That's correct. The whole concept of the DMF was instituted when they wanted to have this generic model, if you will. So the CMO company argued that we didn't want to give that information to a pharmaceutical company who could either misuse it, who could give it to somebody else. So

they created this DMF. So everything within the context of the DMF is confidential.

THE COURT: Therefore, tying it together, once an API supplier has filed a DMF, they are less likely to be interested in entering into a contract with an exclusivity provision because? Could you explain.

THE WITNESS: The main reason is, you want to make volume, even if it's a smaller volume product. It doesn't matter the scope of the project. The more customers you have, the more likely you are going to be able to sell your material.

Also, it will be an advantage because then you will start to develop a relationship with a company, so the company being the pharmaceutical company.

So, as I said, it's not a good example, but it's almost it's like an advertisement. I'm making this. I can make this. I have a DMF. I am going to be able to support you. The more I make, the lower my costs are. The better my economics are, the more profit I'll make.

The other side of it is, you reduce your risk, you from the CMF point of view. If I only offer it to you, again, using Vyera as an example, what if they have a bad year? What if they don't do well in the marketplace? What if somebody else comes in, like a generic, another generic, and does a better job? There are things that they can do to do that.

One, I lose market share as the CMO. But, more

important, as it goes down, my costs go up. Not just for the product. Because keep in mind that a CMO, when they look at their overhead cost, it's based on how much they make, how much material, not necessarily one product. So the more products I make, the lower my overheads are and the more profit I have. I have reduced my risk as the CMO so I could support that production. I reduced my cost because I continue to make more. It's their advantage to have that type of thing. For these kinds of products, that's the case.

THE COURT: In a bargaining situation, if you, the manufacturer, have filed the DMF so the world knows that I have a manufacturing process for this API and I'm available to the world for contracts to supply you with this API, the DMF is filed. That news is out there.

THE WITNESS: Correct.

THE COURT: Now I'm, from the point of view of the pharmaceutical company, coming to the manufacturer and saying, yes, I know. The world is aware that you are a producer of this API.

THE WITNESS: Correct.

THE COURT: But I want to be your only purchaser in America. I want an exclusivity provision. Even though everyone else, every other pharmaceutical company in America knows you have produced this API, I want you only to sell to me.

I have to provide you in this hypothetical with incentives because you are depriving yourself, you, the manufacturer, are depriving yourself of alternative outlets for your API.

THE WITNESS: Correct.

THE COURT: And those incentives could be promises and forecasts of a growth in the pharmaceutical company's business for not just only supplying that API, but maybe other products that the manufacturer produces.

THE WITNESS: Correct.

THE COURT: We won't go to your competing manufacturers. We will instead come to you and purchase other products from you.

THE WITNESS: Correct. I think the other part of it also is, once you start to build that relationship, it costs money to develop a product because you have to audit plans, you have to have that relationship. And, in my experience, when you put a face to the project, things tend to go a lot smoother.

As a consultant, when I'm working with a pharmaceutical company, and that's where a lot of my business is interfacing with the contract manufacturer, the first thing I do is try to get the two parties in the room so you can start to develop that relationship. Because I can assure you in this these types of projects something is going to go wrong. Those

are relationships that help.

But also when you talk about the DMF, again, these aren't being done in a vacuum. You have people talking constantly. If I'm making pyrimethamine for you, my business development guy is going to go in there and say, I am making this. What else are you looking at?

And Vyera may be a little different because it only has the one product essentially at this time. It has a few that they are thinking about. Some of them were, as I heard yesterday, were more line extensions, which just means more volume of that product, not of everything else. There is a dynamic going on between both parties throughout the whole course of the time.

In many of the generics, especially on the market today, the contract manufacturer will actually start working on those products very early on. I have worked on generics that the generic product is made and the ANDA is submitted almost the day that it gets approved by the innovator. This could be seven or eight years in advance you're starting to work on the development of it so that you are ready when it becomes a generic three or four years later.

THE COURT: Let me make sure I understand what you just said.

You are saying that the manufacturer of the API and a generic not infrequently will work hand in hand so that they

are both developing their processes at the same time.

THE WITNESS: Not exactly. You have the right idea.

But what I'm saying is, the generic company will say, look, they go to Fukuzyu and they say, you know what, we are making this product. We have been working with you. We are looking to develop these two products and maybe they are five or six or seven years out.

So then Fukuzyu will say, OK, let me look at it. They will go into their lab. They look at research. If you go on the Internet for a lot of the major CMOs, you will not only see a product line, you will see a development line.

Again, this is an indication, these are things, we don't have them. We don't have a DMF. We don't even have a process. These are the things we are looking at. Again, this interaction is going on. It's not a vacuum, is all I was trying to say.

There is a lot of discussions and all of that. When I was doing more of this as a BD person, business development person, as you move up the proverbial chain, when I was the person calling on the generic house, one of the first things you did is, you talked about what was next. If you are doing a good job on one, you get the next one.

In the case of Fukuzyu, for Vyera, in principle, when Vyera bought the product, Fukuzyu was the only supplier for the product because he was the only one that was approved.

THE COURT: By the FDA.

THE WITNESS: By the FDA, yes.

Since no one else was in the submission that was sent to the FDA by the original GSK, then Impax and then eventually Vyera, Vyera had no choice. It's not like they could say, well, I'll use RL Fine. They had to go through this whole process of getting the approval. That could take some time.

THE COURT: That is, if they went to RL Fine, as opposed to Fukuzyu, they would have to go through an entire process to get RL Fine approved?

THE WITNESS: Exactly. My point that I was trying to make earlier is that without that approval, in principal you can't make the material. Yes, you can make it. But then you better go through that long period of getting the approval.

I don't know the exact number today, but in my business we review with the FDA, because they print some of this, how many applications are in the submissions, how many submissions -- how many applications for an approval.

The FDA has been backlogged at times with over 5,000 submissions that are being reviewed. That could take several years. I had a client once that wanted to amend their submission and in this case this would be an amendment to a submission.

Because it was going to take so long and the amendments go on the bottom of the pile, the new submissions go

on the top. They really just resubmitted a whole new thing, so they were higher on the list. Because it takes long and it's an uncertainty in the time.

In the case of Fukuzyu, this is why I said I don't think RL Fine mitigates the risk, is because I can't make the product and no one is doing anything to get me approved in a reasonable amount of time because in one respect I don't know the time. The estimate is two years, approximately, for just the review part of it. What I do I do for two years?

THE COURT: Thank you.

Do counsel have questions for the witness based on the questions I have placed to him?

MR. PERLMAN: Nothing for plaintiffs, your Honor.

MR. PARKS: Nothing for defendants, your Honor.

THE COURT: Thank you. You may step down.

THE WITNESS: Thank you.

(Witness excused)

THE COURT: Next witness.

MR. MEIER: Your Honor, my colleague, Lauren Peay will handle the next witness for the government. We call Dr. W. David Hardy, M.D. to the stand.

THE COURT: Dr. Hardy, if you would come up here, please, and take the witness stand.

Excuse me, Mr. Bruno. If you could just stay one minute.

Thank you and thank you for your patience. I just wanted to confirm that I had no other questions. Thank you.

WILLIAM DAVID HARDY,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

THE COURT: Dr. Hardy, you are about to be handed a document which I believe is your direct testimony.

MS. PEAY: Your Honor, may I approach the bench and the witness with copies?

THE COURT: Thank you. What's the exhibit number for Dr. Hardy's affidavit?

MS. PEAY: It is Government Exhibit 8003.

THE COURT: Dr. Hardy, if you could turn to page 36 of your exhibit, I believe you authorized someone to electronically sign your name on page 36, is that right?

THE WITNESS: That is correct, your Honor.

THE COURT: Before you gave that authorization, did you read this document with care?

THE WITNESS: Yes, I did.

THE COURT: Do you swear to the truth of its contents?

THE WITNESS: Yes, I do.

THE COURT: Any objection other than those already -- I don't think I have any already made. Any objection to receipt of 8003.

MR. McCONNELL: No objection.

THE COURT: 8003 is received.

(Government Exhibit 8003 received in evidence)

THE COURT: Cross-examination.

CROSS-EXAMINATION

BY MR. McCONNELL:

Q. Good morning, Dr. Hardy. How are you?

A. Good morning. I'm fine. Thank you.

Q. In describing your expertise in this matter you point out that you have treated well over 1500 HIV AIDS patients over your 30-year plus career, is that correct?

A. That is correct.

Q. Are you familiar, Dr. Hardy, with the direct testimony that Professor Hemphill intends to offer in this case?

A. No, I'm not.

Q. Professor Hemphill intends to testify that the most recent available estimate suggests that there are slightly less than 10,000 cases of toxoplasmosis per year in the United States. Do you agree with that estimate from Professor Hemphill?

A. Not ever really counting the cases, I'm not really an expert in terms of how many cases there are or in terms of the diagnosis, treatment, prevention.

Q. In your clinical experience do you believe the number to be more or less than 10,000 per year?

MS. PEAY: Objection, your Honor. This is a question that's outside the Scope of the witness' direct testimony.

THE COURT: Overruled.

You may answer.

A. I would have no good basis to make a good judgment whether that number is correct or not.

Q. According to your direct testimony in this case, Dr. Hardy, you have treated roughly 400 patients for toxoplasmosis over the course of your entire career, is that right?

A. My estimate is somewhere between 200 and probably 350, is best I can say.

Q. According to your testimony in this case, about 200 of those 200 to 350 toxoplasmosis patients you treated with FDA approved pyrimethamine, is that correct?

A. That is correct.

Q. So for the few cases to the 150 cases, based on your total estimation of patients that you have treated, those patients received a treatment other than FDA-approved pyrimethamine, correct?

A. To my best estimate, that would be true.

Q. Dr. Hardy, I'd like to discuss a little bit your clinical background with respect to treatment for toxoplasmosis. OK? You began your clinical experience with toxoplasmosis as a resident physician from the period 1982 to 1986, correct?

A. My residency was actually '82 to '84, but, yes, that would be close to correct.

Q. During that period of time of 1982 to 1986, you would

prescribe pyrimethamine and sulfadiazine for a toxoplasmosis patient unless he or she had an allergy to a sulfonamide antibiotic, correct?

A. That is correct. In terms of the treatment of active toxoplasmosis disease usually in the brain.

Q. At some point between 1982 and 1986, the FDA approved pyrimethamine for toxoplasmosis, correct?

A. I don't know the exact date, but I do know that pyrimethamine has been approved by the FDA for the treatment of toxoplasmosis, yes.

Q. Do you remember being deposed in this case on July 27, 2021, Dr. Hardy?

A. Yes.

Q. At your deposition you testified that you believed that some point between 1982 and 1986, the FDA approved pyrimethamine for use for patients with toxoplasmosis. Do you agree with that testimony?

A. I do remember my deposition, and I faintly remember that date. It may have been actually earlier, but I know it has been approved by the FDA. It may have been done earlier than that, but I am not exactly sure of the date.

Q. Would it be fair to say that by 1986 the FDA had approved pyrimethamine for treatment for patients with toxoplasmosis?

A. That is my best understanding and recollection, yes.

Q. So during that period of 1982 to 1986, you did not rely on

any published guidelines in order to select that course of treatment for toxoplasmosis patients because no published guidelines existed at that time yet, correct?

A. That is true.

Q. During this period of 1982 to 1986, the approximate failure rate for the pyrimethamine treatment regimen for acute active toxoplasmic encephalitis was about one-third, right?

A. I don't have good data to support that, but, to my best recollection, in the early days of the AIDS epidemic, that was a pretty good estimate, yes.

Q. Now I'd like to move to the late 1980s, to the period 1986 to 1991. Is that OK?

A. '86 to '91. OK.

Q. Between 1986 and 1991, the number of toxoplasmosis patients that you were treating each year increased to about 36 patients per year, correct?

A. Yes, approximately 36 per year.

Q. And the only treatment regimen that you used during this time to treat active toxoplasmosis was a pyrimethamine-based regimen, correct?

A. To the best of my recollection, that was my primary -- that was my primary regimen for treatment, yes.

Q. The failure rate of the pyrimethamine-based regimen remained the same for the period 1986 to 1991 for active toxoplasmosis patients, correct?

A. Again, I have no data to prove that, but I would estimate that knowing what was happening, AIDS epidemic during those years, that that high failure rate would continue, yes.

Q. Now I am going to move into the early 1990s. I am going to discuss a drug -- I am going to try my best -- trimethoprim sulfamethoxazole. Are you familiar with that drug?

A. Yes, I am.

Q. Would it be OK if I referred to that drug today as either TMP-SMX or Bactrim?

A. That's fine with me.

Q. Those can be used interchangeably, sir?

A. Trimethoprim sulfamethoxazole is a generic name, TMP-SMX is an acronym for that name, and Bactrim is actually a brand name for that product.

Q. Sometime around 1991, physicians treating toxoplasmosis got lucky in that it was discovered that TMP-SMX not only prevented pneumocystis carinii pneumonia, but was also fairly good at preventing toxoplasmic encephalitis, correct?

A. I don't remember the exact year that that was recognized, but I do remember that, from large pneumocystis prevention studies, there was also a decrease not only in the occurrence of pneumocystis, but also, secondarily, decrease in occurrence of toxoplasmic encephalitis, yes.

Q. Within one year of that discovery, by 1992, TMP-SMX studies began to demonstrate decreases in the occurrence of active

toxoplasmosis, correct?

A. Again, the dates to me are not entirely definitive. I do know that as more TMP-SMX was being used for the prevention primarily of pneumocystis pneumonia that there was some decrease in the occurrence of toxoplasmosis plastic encephalitis as well.

Q. With TMP-SMX you get the benefit of treating two opportunistic infections with one drug, isn't that right?

A. To be more specific, you get the benefit of preventing two opportunistic infections. It's a complicated situation. But the primary reason that TMP-SMX is used for prophylaxis of toxoplasmic encephalitis is because commonly the patient is already taking it to prevent pneumocystis pneumonia. It is simply continued.

Q. And studies showed that TMP-SMX was effective as a prophylactic for toxoplasmosis, correct?

A. Correct. Studies have shown that.

Q. In fact, around this time you wrote a couple of textbook chapters documenting the use of TMP-SMX to prevent both pneumocystis pneumonia and toxoplasmosis around that time, right?

A. Sometime in the early '90s, yes. I wrote chapters reporting that, yes.

Q. Eventually, TMP-SMX became the recommended medication for primary prevention of toxoplasmosis, correct?

A. Yes. That is what our guidelines say.
Q. According to your expert testimony in this case, Dr. Hardy, the three distinct goals for treating and preventing toxoplasma encephalitis are treatment of the active toxoplasmosis disease, primary prophylaxis, which is preventing the development of active disease, and secondary prophylaxis, which is maintenance therapy to prevent recurrence of the active disease. Is that correct?
A. Yes, that is correct.
Q. Today you consider TMP-SMX to be the gold standard for primary prophylaxis for toxoplasmic encephalitis, correct?
A. Yes, I consider it to be the most highly recommended agent for the primary prevention of toxoplasmic encephalitis.
Q. Do you remember testifying at your deposition, Dr. Hardy, that you considered TMP-SMX to in fact be the gold standard for primary prophylaxis for toxoplasmic encephalitis?
A. I don't remember that exact term gold standard, but I cannot equivocate with it. It is the number one recommended option, yes.
Q. So you would agree with me that TMP-SMX is the gold standard for primary prophylaxis for toxoplasmic encephalitis?
A. Yes.
Q. Now, another benefit of TMP-SMX is that it can be administered in intravenous form, correct?
A. Yes, that is correct.

Q. And a pyrimethamine-based regimen, on the other hand, requires that the patient take several pills per day, correct?
A. A total pyrimethamine regimen, yes, does require that. The number of pyrimethamine pills is low. The number of pills that go along with the other medication, sulphadiazine, is very high. But the regimen itself does contain many pills, yes.
Q. I remember reading in your deposition that a pyrimethamine-based regimen patient would be taking approximately nine tablets per day. Is that right?
A. That is correct.
Q. And the pyrimethamine-based pill regimen is sometimes a limiting factor when a patient cannot swallow a pill reliably, correct?
A. Yes. In the situation where the patient is obtunded or comatose and cannot reliably survive pills, an intravenous form of treatment is sought.
THE COURT: Obtunded meaning?
THE WITNESS: Unable to -- have a decreased mental alertness.
THE COURT: Thank you.
Q. For that type of patient, Dr. Hardy, that you just described, intravenous high dose TMP-SMX can be useful to assure adequate drug delivery, correct?
A. That is correct.
Q. I'd like to turn our discussion to another drug,

atovaquone. Are you familiar with that?
A. Atovaquone is a drug I'm familiar with.
Q. Atovaquone is an alternative treatment for treating toxoplasmosis, correct?
A. Yes, that is true.
Q. And you started to use atovaquone to treat active toxoplasmosis sometime after 1991, correct?
A. No, I don't believe that is correct. Until pyrimethamine became difficult to obtain, my number one choice, as per guideline recommendations, to treat active disease from toxoplasmosis in the brain was pyrimethamine plus sulphadiazine or pyrimethamine plus clindamycin. Atovaquone has always been an alternative, second or third choice regimen.
Q. Dr. Hardy, that was not responsive to my question. My question was simply that you did not start using atovaquone at all in any respect to treat active toxoplasmosis until sometime after 1991, correct?
A. Sometime after 1991, yes. It wasn't available at the time until after that date I'm sure.
Q. Between 1991 and 1996, you participated in at least two studies using atovaquone for both active toxoplasmosis and for pneumocystis carinii pneumonia that were fairly successful, correct?
A. I do remember participating in some studies investigating the use of atovaquone in those diseases, yes.

Q. Those studies showed that it was effective, correct?
A. I would have to review the studies to really understand and make a decision whether -- what the term effective means. But I remember participating in them as a clinical research site.
Q. Fair enough with the term effective.
Do you remember at your deposition testifying that those studies were fairly successful, Dr. Hardy?
A. I think the term fairly successful is one I would agree with. Again, it's put into the context of a high-mortality disease that was untreatable in many ways, and fairly successful could be taken in many different ways because of that.
Q. But you agree with it, correct?
A. Yes.
Q. So before 1991, in the 1980s, when you were seeing many patients a year during the HIV AIDS epidemic, TMP-SMX and atovaquone were not used to treat patients with toxoplasmosis, correct?
A. That is correct.
Q. From 1991 to 1996, according to your direct testimony in this case, the number of patients you saw fortunately went down a bit to about 20 patients with toxoplasmosis per year, correct?
A. Yes, that is correct.
Q. Your primary prescription choice for those patients that

presented with active toxoplasmosis was a pyrimethamine-based regimen during that time, correct?

A. Yes, that is correct.

Q. In that 1991 to 1996 time frame, you also had an alternative to pyrimethamine-based regimen and had the ability to prescribe TMP-SMX for active toxoplasmosis, correct?

A. TMP-SMX is, again, an alternative second or line choice. It was available, and I did not use it frequently, no.

Q. But it is possible that you did prescribe TMP-SMX for toxoplasmosis patients during that time, correct?

A. It is possible that I may have prescribed it in the case where an intravenous form of medication was necessary because of a lack of oral route of administration in a patient who could not swallow pills.

Q. In that same time frame, as an alternative to a pyrimethamine-based regimen, it is also possible that you prescribed atovaquone for active toxoplasmosis patients, correct?

A. Yes, it is possible. I would -- I do not remember doing it frequently, however.

Q. So since the introduction of TMP-SMX and atovaquone in the early 1990s, there are now three to four alternative treatments for treating active toxoplasmosis, correct?

A. Yes. Although I would correct the descriptive term from alternative to secondary or tertiary recommended regimens.

Q. Do you remember at your deposition, Dr. Hardy, characterizing TMP-SMX and atovaquone as alternatives for treating active toxoplasmosis?
A. Yes, I do.
Q. You testified truthfully at your deposition, correct?
A. Yes, I did.
Q. And the survival rate for your patients with active toxoplasmosis encephalitis was no different whether you treated them with Daraprim or TMP-SMX, correct?
A. That's a complicated question because of the time periods in which I was treating patients with different medications and the availability of antiretroviral therapy, which became available after 1996.
MR. McCONNELL: Justin, could you please pull up Dr. Hardy's deposition for me, please, page 44.
Q. You were asked at your deposition Dr. Hardy: So do you have an estimate of approximately what percentage of toxoplasmic encephalitis you treated during that time period with treatment regimens other than pyrimethamine sulphadiazine or pyrimethamine clindamycin, correct?
THE COURT: What time period is that question referring to?
MR. McCONNELL: The middle 1990s, your Honor.
A. From '91 to '96?
THE COURT: Is that the time period, counsel?

MR. McCONNELL: I believe so, your Honor, yes.

Q. Do you see the question, Dr. Hardy?

A. Yes.

MS. PEAY: Objection, your Honor. This is improper impeachment or improper refreshing of the witness' recollection.

THE COURT: We don't have the question yet. We have the question asked at the deposition but not the question asked at the trial.

Wait until the question is finished.

We now know what the question asked at the deposition is referring to, a period of time between 1991 and 1996. The answer?

MR. McCONNELL: Yes, it's between 1991 and 1996. I apologize, your Honor. I can continue.

The opposing counsel at the deposition asked for clarification of whether the question referred to active toxo or just generally, and then the examining attorney clarified toxoplasmic encephalitis and then the witness asked if he could clarify that. And then the witness answered: OK. I would have to say the survival rate of the patient was no different.

Q. Do you agree with that testimony, Doctor?

A. Yes, I do agree with it based on my deposition.

THE COURT: Before antiviral therapy for AIDS patients became available in 1996, the survival rate for those treated

with the two alternative therapies was no different, as you recollect?

THE WITNESS: As I recollect, in that pretherapy -- antiviral therapy period, they were about the same.

THE COURT: Thank you.

Q. Dr. Hardy, moving past 1996, you have continued to prescribe primarily TMP-SMX for primary prophylaxis of toxoplasmosis, correct?

A. Yes, that is correct.

Q. But from 2000 to 2015, you do not know what percentage of toxoplasmosis cases in the United States were treated with FDA-approved pyrimethamine tablets, correct?

A. I do not have data to support an answer for that. I can tell you that the number of toxoplasmosis cases decreased sharply after 1996. And to know exactly how and what they were treated with would be a difficult -- it would be a guess on my part.

Q. So the treatment choices of your colleagues in the medical field between 2000 and 2015, you don't have data to support whether they were prescribing FDA approved pyrimethamine tablets or some other treatment for toxoplasmosis during this time, right?

A. I can say that the CDC, NIH, IDSA, HIVMA sponsored guidelines continue to recommend a pyrimethamine-based regimen. I do not have data to prove how patients were actually treated.

Q. Thank you. That was my question regarding the data.

Those guidelines were developed in response to the AIDS and HIV epidemic in the 1980s, correct?

A. I believe they were first put together in the late 1980s, early '90s, in order to be able to give physicians direction of how to treat what were previously very rare infections.

Q. Unfortunately for those patients, at that time, in the late 1980s, there were many more toxoplasmosis patients than there are today to be able to do more effective studies on effective treatment, correct?

A. That is correct.

Q. But by the time TMP-SMX and atovaquone were introduced in the 1990s, there were few toxoplasmosis patients to run similar studies, correct?

A. It would really depend upon the time period. Prior to 1996, the number of toxoplasmosis cases was about the same as they were in the 1980s, maybe even greater, because there were more patients that being were treated. After 1996, with the advent of antiviral therapy, the number of all opportunistic infections, including toxoplasmosis, markedly decreased.

Q. Just to be clear, the guidelines recommending FDA-approved pyrimethamine came out in the late 1980s, before TMP-SMX or atovaquone were used to treat toxoplasmosis, correct?

A. I can say that with definition for atovaquone because it was not available. TMP-SMX has been available since the 1970s,

so I can't really give an estimate, whether it was ever used to treat toxoplasmosis encephalitis. It may have been. I don't know. I have no data to support it one way or the other. But it was not seriously tested in clinical trials until the early 1990s.

Q. Thank you.

I want to move, Dr. Hardy, to the post 2015 to present time frame. Is that OK?

A. Of course.

Q. In 2015, you encountered some difficulties obtaining pyrimethamine for your patients due to price, correct?

A. Correct.

Q. After a price increase on pyrimethamine, about 85 to 90 percent of the time that you tried to obtain pyrimethamine sulphadiazine it was unsuccessful, correct?

A. That is correct.

Q. When you could not obtain a pyrimethamine-based regimen, you prescribed TMP-SMX as an alternative in a majority of those cases that you just described, correct?

A. Yes, I did.

Q. When infectious disease experts could not obtain a pyrimethamine-based regimen during this time, some started prescribing compounded pyrimethamine as an alternative as well, correct?

A. Yes. I have heard of that and have seen some limited

research articles published.
Q. Albeit based on, as you said, very limited data, TMP-SMX may be the most commonly used medication for active toxoplasmosis since 2015 in the United States, correct?
A. I cannot give an opinion about what is most commonly used. That's not part of my expertise. So I really can't give you a good answer on that.
Q. At conferences that you have attended for your industry you have learned that the unavailability due to the price of pyrimethamine over the past few years has made TMP-SMX the most commonly used medication for toxoplasmosis outside of the United States, correct?
A. Again, I have no data. I cannot remember whether or not I heard that at a conference or not. I do know that the lack of availability of pyrimethamine has greatly affected the choice for treatment of this life-or-death disease in which therapy must be started within a very short period of time after diagnosis.
Q. Since the price increase of pyrimethamine after 2015, you are not aware of any published data establishing a negative impact on patient care, correct?
A. No, I'm not aware of any published data.
Q. You do not know what percentage of pyrimethamine prescriptions in the United States are prescribed to treat active toxoplasmosis, correct?

A. Again, that's not part of my expertise. In looking at the marketing or use of pyrimethamine.
Q. So you don't know, correct?
A. I do not know.
Q. You do not know what percentage of active toxoplasmosis cases in the United States are treated with FDA approved pyrimethamine tablets, correct?
A. Again, I have done no survey. I have seen no research. I have no data to confirm that number in any way.
Q. You do not know what percentage of active toxoplasmosis cases in the United States are treated with compound pyrimethamine either, correct?
A. Again, I have no data to be able to make a reliable answer to that question.
Q. For your expert work on this case you did not make any attempt to determine those percentages, did you?
A. No, I did not.
Q. Now, you have testified on direct that you have designed, conducted, and reported the results of over 30 clinical trials testing investigational medications for treatment and prevention of AIDS-related opportunistic infections, correct?
A. That is correct.
Q. But you are not aware of any peer-reviewed studies that have looked at the frequency of use of different treatment regimens for toxoplasmosis during any of the time periods

between 2000 and the present, correct, Dr. Hardy?
A. Frequency of use is not usually a topic published in medical journals, as opposed to toxicity and efficacy, but I have not seen or am I aware of any articles that look at that question, no.
Q. In your clinical experience, is one of the reasons why there are no such peer-reviewed studies is because there are an insufficient number of toxoplasmosis patients to run such a rigorous study?
A. That is correct. The number of cases of toxoplasmosis has decreased markedly. Among HIV-positive persons it has remained somewhat consistent, among other immunocompromised patients, such as those receiving stem cell or bone marrow transplants, but that number is still pretty low.
Q. Again, unfortunately, you would agree with me that none of the treatment regimens, pyrimethamine-based regimens, TMP-SMX or atovaquone, would be capable of actually eradicating latent toxoplasmosis in patients, correct?
A. Yes, that is correct.
Q. As far as you are aware, Dr. Hardy, there has not been a new medication approved to treat toxoplasmosis since atovaquone, which, as we discussed, came out in about the mid 1990s, is that correct?
A. That is correct.
Q. You testified at your deposition that the development of

new medications for toxoplasmosis has not been a high priority for the biopharmaceutical industry whatsoever and that is primarily because the diseases, while life threatening and several and always needing treatment, does not occur at a high-enough prevalence to make development of a drug for this disease profitable, correct?

A. I would have to see the exact words from my either direct testimony or deposition that you just read. But, in general, yes, that is a belief of mine, yes.

Q. If you agree with that testimony I don't think we have to go back and show you, if that's OK with you, Dr. Hardy.

You went on to note at your deposition that clinical trials comparing the efficacy of pyrimethamine to TMP-SMX are not feasible any longer because so few patients are developing toxoplasmosis these days, correct?

A. That is correct.

Q. For your engagement on this case, you have not personally done a statistical survey of infectious disease practitioners preferences for treating toxoplasmosis, correct?

A. I have not and am not aware of any either.

Q. In your direct testimony, Dr. Hardy, you testified that the opportunistic infections guidelines contain treatment guidelines for the treatment of toxoplasmosis, correct?

A. Yes, they do. That is correct.

Q. But you would agree with me, though, that whether a single

physician in his or her own personal practice follows those guidelines is a matter of personal physician choice, correct?
A. What a physician does in terms of treatment is always their choice. What kind of guidelines they follow is always their choice. Whether they endeavor to practice evidence-based medicine or not is always their choice.
Q. According to Professor Hemphill's direct testimony that he intends to give to this Court, pyrimethamine is considered the standard of care for all manifestations of toxoplasmosis. Do you agree with that opinion of Professor Hemphill?
A. In large part, that is very true. There are -- there is one specific type of toxoplasmosis that is treated with a different drug called spiramycin in a very specific clinical situation. But in all other situations in which toxoplasmosis is being treated, yes, that is true.
Q. If one of your infectious disease colleagues treated a toxoplasmosis patient with TMP-SMX instead of pyrimethamine, would you consider that to be a breach of that physician's standard of care?
A. To judge a physician's standard of care is not my job or am I an expert in judging physician's care. Again, it is a personal choice based upon teaching, experience, etc.
Q. Are you able to think of situations where a physician would not prescribe FDA-based pyrimethamine and for a toxoplasmosis patient and still be within the proper standard of care?

A. Certainly in a situation where a patient cannot take oral medication, the use of intravenous TMP-SMX is in fact recommended by the guidelines as a route of administration and really the only medication that is available to treat such a patient. So in that situation, yes, I would say that is a proper and recommended form of treatment.

Q. That's just one example, correct, Dr. Hardy? There are other situations besides intravenous indication for a toxoplasmosis patient where a colleague of yours could prescribe TMP-SMX and be within the proper standard of care for that patient, correct?

A. Again, each physician practices medicine by their own style and methodology. How they do that is up to them.

Q. Is that answer yes?

A. That answer is, yes, I'm aware of that happening.

Q. When you have heard of that happening, you haven't thought that your colleague was breaching a standard of care to his patient, his or her patient, correct?

A. Again, I cannot judge my colleagues' standard of care and how they treat their patients.

Q. If one of your infectious disease colleagues treated a toxoplasmosis patient with TMP-SMX instead of pyrimethamine, only because of the price of pyrimethamine, would you consider that to be a breach of that physician's standard of care?

A. Having done that myself, because of the price and the

availability of pyrimethamine and by necessity of needing to start a medication in a very short period of time, the immediate availability of TMP-SMX is what I have done myself, so I would not judge a physician for doing that. It's a necessity of the current marketplace.

Q. As part of your engagement for this case, Dr. Hardy, you had a conversation with some members of the Federal Trade Commission in April or May of 2019 regarding the general issue of drug access to pyrimethamine in the form of Daraprim for the treatment of toxoplasmosis, your personal experience, and what you knew as the leader of HIVMA, correct?

A. I do remember having a telephone conversation with someone from the FTC about this topic, and I was the chair of the board of HIVMA at that time.

Q. Is it fair to say that that conversation happened sometime in April 2019?

A. I believe that was about the day, yes.

Q. Now, do you remember sending an e-mail on April 3, 2019 to over 30 of your fellow infectious disease colleagues regarding this issue?

A. Yes, I do.

Q. In that e-mail you stated to your 30-plus infectious disease colleagues that the Federal Trade Commission has asked you to testify, has asked you, Dr. Hardy, to testify regarding whether this enormous price hike of pyrimethamine has limited

patients' access to this life-saving drug. Do you remember sending that e-mail?

A. Yes, I do.

Q. And your intent in sending that initial e-mail from April 3 of 2019 was to look to your fellow infectious disease colleagues working in urban areas that have historically cared for many HIV-positive persons to look for cases of problems with access to pyrimethamine, correct?

A. My intent was to simply, as you alluded to before, do a very informal survey of colleagues who I know worked in areas where HIV-AIDS had been and still was prevalent to better understand what their experience had been in terms of treating toxoplasmosis.

Q. At your deposition you could only remember receiving two responses from your colleagues to that e-mail, correct?

A. I believe there were overall three, as I look at the records more carefully, but yes at least -- I believe there were three responses that I can remember.

Q. So you e-mailed 30 plus colleagues and you got three responses, correct?

A. Correct.

Q. And one of those responses to your inquiry regarding the FTC's questions was an April 4, 2019 e-mail that you received from Dr. Rajesh Gandhi, correct?

A. I believe I did receive something from Rajesh Gandhi. I

can say for sure that was him. But go ahead.

Q. Would it refresh your recollection, sir, to see the e-mail?

A. That would refresh me. Yes. Please do.

MR. McCONNELL: Justin, could you please bring up DX-456 to help refresh Dr. Hardy's memory.

Q. Dr. Hardy, please take a moment to review the e-mail and let me know when you have completed your review.

A. Yes, I do remember this e-mail.

Q. Does the e-mail from April 4, 2019 reflected in DX-456 refresh your recollection, Dr. Hardy?

A. Yes, it does.

Q. Dr. Gandhi responded to your e-mail to provide you with an update regarding Massachusetts General Hospital's issues with pyrimethamine access, correct?

A. Correct.

Q. The MGH there in the e-mail stands for Massachusetts General Hospital, correct?

A. That is correct.

Q. Dr. Gandhi told you that we at Massachusetts General Hospital have been able to access pyrimethamine through a noncommercial source but that that will no longer be the case as of September 2019. As a result, our patients will either need to use the commercial product, 400 to $900 per 25-milligram tablet, or we'll be forced to switch to trimethoprim sulfamethoxazole instead?

A. That is correct.
Q. And trimethoprim sulfamethoxazole is the TMP-SMX that we have discussed today?
A. That is true.
Q. Is it possible, Dr. Hardy, that the noncommercial source referenced by Dr. Gandhi was a reference to compound pyrimethamine?
THE COURT: Sustained.
Q. Dr. Gandhi also noted that the Massachusetts General's toxoplasmosis patients will either need to use the commercial product or be forced to switch, correct?
A. That is the reading of his e-mail, yes.
MR. McCONNELL: You can take that down, please, Justin.
Q. You did not rely on that e-mail from Dr. Gandhi in offering your expert report or testimony in this case, correct, Dr. Hardy?
A. No, I did not.
Q. Dr. Hardy, you will agree with me that the research finds, although not conclusively, that TMP-SMX is a well-tolerated alternative to pyrimethamine-based treatment regimens for toxoplasmosis patients, correct?
A. It is true that there have been two studies, randomized trials. One was never finished. One was problematic. And the results -- the conclusions from those studies were exactly as

you said, yes.

Q. You in fact cited to at least one of those studies in book chapters and articles that you have written over the course of your career, correct?

A. Yes, I probably have. I don't remember the exact citation, but having written many book chapters and articles on this topic, I probably did use those because they were the only ones available.

Q. We talked a little bit earlier, as part of your engagement on this case you sent out an e-mail to your colleagues and you got three responses. We just checked one. I'd like to discuss another one with one of your colleagues, but the identity of that person has to remain confidential. Do you understand that, Dr. Hardy?

A. I understand that. I am aware.

(Continued on next page)

Q. Do you remember the contents of that email back and forth that you engaged in with that colleague of yours that responded to your inquiry?
A. Yes, I do.
Q. So that colleague of yours responded to your request and informed you that: "I think what we have learned is that there are better tolerated and less toxic alternatives. We either use Bactrim or the combination of clinda/atovaquone, which ironically is what ophthalmologists have been using for ocular toxo for years, and I am unaware of any poor outcomes in transplants or HIV from not having pyrimethamine," correct?
A. I do remember that email, yes.
Q. And you responded to your colleague that: "The scant research seems to find, although not conclusively, that TMP/SMX is a well-tolerated alternative to Pyr-Sulfa or Pyr-Clinda for CNS toxo and atovaquone clinda regimen is used successfully in ocular toxo," correct?
A. I do remember writing that, yes.
Q. And just for clarity of the record, Pyr-Sulfa is pyrimethamine -- I'm sorry, I shouldn't have even tried.
Dr. Hardy, can you please clarify what Pyr-Sulfa was in your email?
A. By Pyr-Sulfa, I was referring to pyrimethamine and sulfadiazine.
Q. The reference to Pyr-Clinda, what were you referring to

there?
A. Pyrimethamine plus clindamycin.
Q. And CNS, the reference there to CNS toxo, that's central nervous system, correct?
A. Correct.
Q. The atovaquone/clinda regimen that's referred to in that email is an alternative treatment that has been used in ocular toxoplasmosis patients, correct?
A. There are case reports that that has been used, yes.
Q. And then you followed up with that colleague in a subsequent email and asked: "Do you feel that TMP/SMX or atovaquone/clinda is as effective as pyrimethamine sufadiazine," correct?
A. Can you show me the rest of that email?
Q. I can.
MR. McCONNELL: Justin, if you bring it up.
Your Honor, I believe it has been properly redacted.
Justin, if you could bring it up to refresh the witness' recollection. Sorry, it's DX 453.
THE COURT: Don't publicly display it. Display it just to counsel and the witness and me.
BY MR. McCONNELL:
Q. Dr. Hardy, please let me know after you have had a chance to review the email.
(Pause)

A. Yes, I've read that -- reread that.
BY MR. McCONNELL:
Q. Dr. Hardy, does the email reflected at DX 453 refresh your recollection?
A. Yes, it does.
Q. And at the very bottom of the first page of DX 453 is the question I just referenced where you addressed your colleague with the question, "Do you feel that TMP/SMX or atovaquone/clinda is as effective as pyrimethamine sulfadiazine," correct?
A. Yes, I did ask that question.
Q. And the colleague that you posed that question to responded: "In my opinion, I think Bactrim is as good, better tolerated, less toxicity, and cheaper. I held that stance for years before Martin. The necessary placebo-controlled trials were never done and unlikely to be ever done," correct?
A. Correct.
Q. And she also responded to your question that: "Pyrimethamine is not available in many parts of the world, and toxo is treated with SMX/TMP. I have not seen data that mortality is higher," correct?
A. That is correct.
Q. Do you have any reason to disagree with that opinion?
A. I accept my colleague's opinion and how this doctor has recommended treatment, which I do not agree with in my own

practice, in my own teaching, in my own training, and primarily because it's not consistent with our treatment guidelines for this disease. But her opinion is her opinion.

Q. You don't think that this physician is breaching a standard of care to her patients, correct?

A. No, I do not.

Q. And then with the other part of your question, regarding clinda/atovaquone, your colleague responded, "As far as clinda/atovaquone, all I have seen are a few cases, and all recovered," correct?

A. Correct.

MR. McCONNELL: You can take that down, Justin. Thank you.

Q. And you did not, Dr. Hardy, rely on that email correspondence with that infectious disease colleague of yours in rendering your opinion in this case, correct?

A. No, I did not.

Q. So you did not do a statistical survey of what your infectious disease colleagues were doing as far as treatment of toxoplasmosis for this case, correct?

A. No. My opinion is based upon a much larger body of evidence called the treatment guidelines, not upon the opinions of two colleagues.

Q. Well, that's actually not -- that's a separate question. I'm just asking -- my first question is just simply: You did

not do a statistical survey of what other physicians were doing as far as treatment for toxoplasmosis for your expert opinion in this case, correct?

A. Not a formal survey, no.

Q. But what you did do is you emailed, roughly, 38 of your infectious disease colleagues for their input to help answer this question posed to you by the Federal Trade Commission, correct?

A. I was curious as to what my colleagues' experience with treating toxoplasmosis in the current era was all about, yes.

Q. Correct. Because the FTC wanted to know whether there were patient access issues because of the high price of pyrimethamine, correct?

A. It was not so much the FTC wanting to know; it was the fact that I was curious myself and wanted to be better informed about if there were issues, that I would understand them better.

Q. And that email to 38 of your colleagues received three responses, two of which we've discussed today, correct?

A. Correct.

Q. The third, I don't believe has been produced in this litigation; is that correct?

A. It is part of the witness packet -- I mean the evidence packet. Yes, I've seen it.

Q. Well, I haven't had the opportunity to see it, but,

regardless, you only received three responses to your inquiry to your 38 infectious disease colleagues, correct?

A. Correct.

Q. And two of those physicians endorsed using Bactrim as an alternative treatment for toxoplasmosis to pyrimethamine-based regimens, correct?

A. Yes. One endorsed it as her recommended regimen, one endorsed it as a have to using the word forced to use TMS/SMX.

MR. McCONNELL: Thank you very much, Dr. Hardy.

THE COURT: We're going to take our midmorning recess. Thank you.

(Recess)

THE COURT: The witness can retake the stand.

Is somebody getting other defense counsel?

COUNSEL: Yes, your Honor.

THE COURT: Thank you.

(Pause)

THE COURT: So any redirect?

MS. PEAY: Yes, your Honor. Lauren Peay, from the Federal Trade Commission. We'll have some redirect.

REDIRECT EXAMINATION

BY MS. PEAY:

Q. Good morning, Dr. Hardy.

A. Good morning.

MS. PEAY: My name is Lauren Peay, your Honor, on

behalf of the Federal Trade Commission, for the government plaintiffs.

Q. And, Dr. Hardy, I'll have a few questions for you in redirect now.

A. Yes.

Q. Dr. Hardy, during your testimony in response to questions from defense counsel just now, you mentioned the guidelines several times.

Do you recall that?

A. Yes, I do.

Q. And, Dr. Hardy, can you explain what the guidelines are that you're referring to?

A. Yes, I can. The guidelines are a compilation of as much available scientific and medical evidence that there is extant to be able to create some very clear and graded recommendations for how to diagnose, treat, and prevent opportunistic infections that were associated with HIV/AIDS.

Q. Who publishes the guidelines?

A. The guidelines are published by the CDC, the National Institutes of Health, the Infectious Disease Society of America, and also the HIV Medical Association.

Q. How are you familiar with the guidelines?

A. I'm familiar with the guidelines because I was trained to refer to them, to use them, to follow them in situations where I ever had questions in terms of diagnosis, treatment, or

prevention of one of the opportunistic infections. I helped create data for them and was part of a group that was specifically involved in the guidelines around pneumocystis and toxoplasmosis, and I use them not only in my own training, but in teaching my trainees and clinical practice, of course.

Q. To make it clear on the record, these guidelines, the opportunistic infections guidelines, they provide guidance for a number of different opportunistic infections, correct?

A. Correct.

Q. Dr. Hardy, do you have an understanding of how these guidelines are developed?

A. Yes, I do.

The guidelines really seek to take into account all laboratory, animal-based models, and clinical research, and even clinical experience where clinical research may be lacking, in order to be able to come up with a consensus of opinion as to how to best diagnose, treat, and prevent these opportunistic infections.

Q. Do you have an understanding of whether the guidelines are ever updated?

A. Yes, they are. The panel is pulled together to review new data when it becomes available in order to see whether that new data will, in fact, impact the current guidelines.

Q. Do you have an understanding of what types of data the guidelines drafters consider in evaluating their guidelines in

deciding whether to update them?
A. The guidelines drafters consider a wide range of data. They prefer it always to be peer reviewed and published. They rarely take into account nonpeer-reviewed data, but they put as a highest priority randomized controlled clinical trials of diagnostic treatment or prophylactic modalities, but accept cohort studies, which are uncontrolled and not randomized, as well as meta-analyses, as well, when randomized controlled trials are not available.
Q. And, Dr. Hardy, do you recall defense counsel asking you about prophylaxis for toxoplasmosis?
A. Yes, I do.
Q. Do you recall also testifying about the treatment of the active disease of toxoplasmosis?
A. Yes, I do.
Q. Are there different treatment goals for toxoplasmosis?
A. Yes, there are.
Q. What are those different treatment goals?
A. The goal for prophylaxis is what I would always consider to be a lower bar to meet in terms of trying to prevent the occurrence of an opportunistic infection in a patient at risk for that infection because of their degree of immune deficiency. The higher bar, in my mind, is always treatment. Once the organism has become active in the person's body, then bringing -- treating that active infection is oftentimes more

difficult, requires longer treatment, and oftentimes more potent treatment, especially combination treatments, in order to be able to bring that infection back under control.

Q. What is the ultimate goal of treating the active infection?

A. The ultimate goal of treating toxoplasmosis in the brain or CNS toxoplasmosis is to put the organism that has become active back into a latent state.

As I said earlier, none of our antibiotics that we use to treat or prevent toxo will eradicate the cystic state of the organism, but the medications are used to keep it in its cystic, inactive state, just like a competent immune system would.

Q. Do you recall earlier defense counsel mentioning another treatment goal for toxoplasmosis, the secondary prophylactic treatment goal?

A. Yes. Sorry. Secondary prophylaxis was commonly used, and still sometimes is used, in order to keep a successfully treated active infection -- keeping it inactive. In the case of toxoplasmosis, before the advent of anti-retroviral therapy, the immune deficiency persisted despite successful treatment of the opportunistic infection. If treatment would have been abruptly stopped, it would only be a matter of time for the organism that was inactive to become active again.

In order to prevent that, we learned that a continuous dose of oftentimes the same medication used to treat the

infection, but at a lower dosage, would be necessary to keep the organism suppressed and in a latent state and not causing harm to the patient.

Q. Returning to the guidelines, do the guidelines provide different recommendations for the three different treatment goals you just testified about?

A. Yes, they do.

Q. And starting with prophylaxis, primary prophylaxis for toxoplasma gondii, what are the guidelines recommendations?

A. For primary prophylaxis of toxoplasmosis gondii, the guidelines recommend a daily tablet of either single strength or double strength TMP/SMX.

I also want to point out that the reason that this is recommended is not only because there has been some data to support that, but for convenience reasons, most patients are already taking TMP/SMX to prevent pneumocystis pneumonia.

And so since those drugs were already being part of the patient's medication regimen, an added benefit was to prevent toxoplasmosis. So the reasoning for using TMP/SMX is most commonly a continuation in the rare case that the patient was not at risk for pneumocystis. Also, TMP/SMX would also still be chosen because it has been shown to be effective.

Q. What are the guidelines recommendations for the treatment of active toxoplasmosis?

A. For active toxoplasmosis, the guidelines give a

pyrimethamine-based regimen, the highest recommendation as A1. Pyrimethamine does need to be combined with a second antibiotic, either sulfadiazine, sulfonamide, or clindamycin.

Q. What do the guidelines recommend for the secondary prophylaxis for toxoplasmosis?

A. For secondary prophylaxis, lower doses of pyrimethamine and sulfadiazine or pyrimethamine and lower doses of clindamycin are recommended.

THE COURT: Say that again? Slow down. I'm sorry.

THE WITNESS: Sorry.

For secondary prophylaxis, or what is also considered to be maintenance therapy, the guidelines recommend lower doses or less frequent dosing of both pyrimethamine plus sulfadiazine, or, if the patient cannot tolerate a sulfa drug, lower doses of pyrimethamine plus clindamycin.

BY MS. PEAY:

Q. Dr. Hardy, do you have an understanding of why the guidelines recommend different treatments for toxoplasmosis depending on the treatment goal?

A. Yes, I do.

Q. What is that understanding?

A. My understanding is that one would always like to prevent an infection if possible. It took us, as AIDS-treating physicians and researchers, several years to figure out that we could do that. So we treated opportunistic infections for many

years until we realized that prevention, both before and after acute treatment, was necessary.

So the goals are different in terms of the immediate life-threatening effects of each disease state. Prophylaxis is used when there is a potential for active toxoplasmosis to occur. Active toxoplasmosis is the life-threatening disease that we hope to prevent, or if we can't prevent it, then to treat it successfully to put it back into a latent state.

Q. Thank you.

Dr. Hardy, you've offered an opinion that FDA-approved pyrimethamine in combination with sulfadiazine or clindamycin is the gold standard for treating active toxoplasmosis, correct?

A. Correct.

Q. Can you explain the basis for that opinion?

A. The basis for that opinion really derives directly from the grading system that the panel of the guidelines uses. It's a well-recognized academic system that is acronymed G-R-A-D-E. I don't remember exactly what the acronym stands for, but it is a very highly analytic way of looking at data and being able to place value and confidence in the data. It results in a number -- excuse me. It results in a letter grade of A, B or C — a being best, C being less — in terms of strength of data, and a number — 1, 2, and 3 — relying on the quality of the data.

So I think the way the guidelines really kind of boil a huge amount of information down is by simply listing what each treatment has been ranked. Pyrimethamine-based regimens with either sulfadiazine or clindamycin receive the highest recommendation of A1, the strongest data with the highest reliability, TMP/SMX receives a grade of B1, less strength of the data, because of being tested less, of it being shown to have much less potency when used in laboratory and in animal models, compared to pyrimethamine, sulfadiazine, and, therefore, this is really, I think, the best attempt at providing guidance to practice evidence-based medicine really going to the level of laboratory tests, animal models, and human clinical experience, and human clinical trials to derive something that will result in an easy-to-read and easy-to-use grading system of recommendations.

Q. Now, in your --

THE COURT: Excuse me. This testimony you've just given about the A1 versus the B1 ratings, is that for the treatment of the active disease?

THE WITNESS: Yes, it is.

THE COURT: Thank you.

BY MS. PEAY:

Q. Dr. Hardy, sticking with the treatment of the active disease, in your written direct testimony, you provided an opinion regarding the use of TMP/SMX for the treatment of

active toxoplasmosis; is that correct?

A. That is correct.

Q. What is that opinion?

A. My opinion of the use of TMP/SMX for the treatment of active toxoplasmosis is really following what the guidelines really recommend, and that is, if the first and most highly recommended — the gold standard — regimen is not available, and a decision to treat this disease has to be made quickly, then one must use other alternative options.

I think it's important to put into context that when a patient with active toxoplasmosis presents to a hospital or medical center, there is very little time to try to procure antibiotics. This is a life-threatening disease immediately, it is affecting the intimate tissues of the brain, and if treatment is not initiated within hours, the patient could, in fact, die or have significant neurologic deficits. So waiting for pharmacy orders, waiting for insurance approvals, waiting for ways to try to obtain a difficult-to-procure antibiotic is really not feasible. Therapy has to be started within hours of diagnosis. And that's why, in the period of time where pyrimethamine became difficult to obtain, TMP/SMX became used much more commonly.

Q. Dr. Hardy, counsel for defendants asked you some questions about some emails that you had with some colleagues that you're connected with through HIVMA.

Do you recall that?

A. Yes, I do.

Q. To the extent that these colleagues expressed a preference for TMP/SMX, is that consistent or inconsistent with the opinions you're offering in this case?

A. One of the opinions — and I underscore the word opinion — and own clinical experience is different than mine, of the opinion I'm purporting here, because I use what I consider to be the highest level of evidence-based medicine treatment guidelines as the way that I make my treatment decisions. I am not perplexed, frustrated, or disappointed at some of my colleagues that have different experiences. I respect their work; I respect their research. They simply have different experiences of treating, different styles of treating, than I do.

Q. And, Dr. Hardy, in your written direct testimony, you offered the opinion that TMP/SMX is not interchangeable with a pyrimethamine-based regimen for the treatment of active toxoplasmosis.

Do you recall that?

A. Yes, I do.

Q. Can you explain the basis for that opinion, that TMP/SMX is not reasonably interchangeable?

A. The reason I feel like it's not readily interchangeable is because this is not a situation in which both have been

recommended as equal options for treatments. There is a clear gradation that our guidelines give us, in terms of the ranking system, of A1 for pyrimethamine-based regimens and B1 for TMP/SMX regimens.

That's the basis of my opinion that they are not readily interchangeable.

Q. Are there populations of patients for whom TMP/SMX is not an option?

A. Yes, there are patients who cannot tolerate sulfonamide because of the sulfamethoxazole that is part of the TMP/SMX.

Q. Can patients who cannot tolerate sulfonamide, can they be prescribed a pyrimethamine-based regimen?

A. Yes, they can. They can be prescribed a combination of pyrimethamine plus clindamycin.

Q. Do you have an understanding of how common sulfonamide intolerances are among patients who are infected with active toxoplasmosis generally?

A. Yes. There is good published evidence that sulfonamide hypersensitivity or allergy is much more common in HIV positive persons than HIV negative persons, being calculated somewhere around 30 to 35 percent of all patients with HIV.

Q. Can TMP/SMX be used in making an empirical diagnosis of active toxoplasmosis?

A. That's also another difficulty with using that drug. To elaborate just a bit, optimally, physicians would like to have

what's called a tissue diagnosis to be able to obtain tissue from the patient in order to demonstrate clearly the infectious organism. In the case of toxoplasmosis in the brain, we're talking about needing to do a brain biopsy, which carries with it a high complication rate in a patient that's already neurologically compromised.

One of the ways that we confirm the diagnosis of CNS toxoplasmosis or toxoplasmic encephalitis is by a positive response to therapy in order to avoid having to do a brain biopsy.

The specificity that pyrimethamine sulfadiazine has for treating toxoplasmosis is also one of its benefits. On the other hand, TMP/SMX was developed to treat primarily bacterial infections. Later on, after its use in the 1980s and '90s, it was found that it could also treat other types of organisms, such as pneumocystis pneumonia or toxoplasmosis. The problem here is that if there's a positive response to TMP/SMX, we do not know for certain that the organism being treated is, in fact, toxoplasmosis. There have been cases of brain -- bacterial brain abscesses and even hemoptysis of the brain that could, in fact, be treated successfully with TMP/SMX, at least partially treated, for some period of time.

So the specificity of how well pyrimethamine-based regimens treat toxoplasmosis are an important part of why we use it.

MS. PEAY: Your Honor, at this time, I have no further questions for the witness.

Thank you, Dr. Hardy.

THE WITNESS: Thank you.

THE COURT: Any recross?

MR. McCONNELL: Sean McConnell, for defendant, Mark Shkreli. Yes, please, your Honor.

RECROSS EXAMINATION

BY MR. McCONNELL:

Q. Hello again, Dr. Hardy.

A. Hello.

Q. Real quickly, you just provided testimony in response to questions from plaintiffs' counsel regarding the gradation of treatment for active toxoplasmosis with a pyrimethamine-based treatment plan being A1 and the SMP/TMX being B2, correct?

A. B1.

Q. B1?

A. Correct.

Q. Sorry.

The reason for that gradation is solely as a result of the guidelines you mentioned in your testimony, correct?

A. The basis of those gradations are based upon the strength of the evidence. That is where the A and B differ in terms of the strength of the data supporting each one of those choices.

Q. Correct.

And you, at the beginning of your redirect, explained the hierarchy of the type of strength to go into that type of evidence for the guidelines, correct?

A. Correct.

Q. So, number one, best evidence would be clinical review trials, correct?

A. Randomized controlled clinical trials are looked upon as the highest level of testing medications, yes.

Q. So, ideally, you would have those types of tests to test the various treatment options for active toxoplasmosis, correct?

A. Correct.

Q. And then you said the number two, if you don't have the ability to do CRTs, the next best type of evidence would be peer-reviewed studies, correct?

A. Would be peer-reviewed cohort studies or what's called a meta-analysis, a systemic review, of a collection of small studies or even case reports.

Q. And just to be clear, there are no available CRTs or peer-reviewed studies establishing the benefits of a pyrimethamine-based regimen versus SMP/TMX that have been published since be 2000, correct?

A. Since 2000? I know that one was published in the 1990s, the one from Italy. There was a second one from Thailand that was published — I don't have the exact date when that was

published. That may have been published after 2000. I don't remember exactly the date on that, but there are two, there are two randomized controlled trials. The one from Italy was small — 77 patients. The problem with that study was that, in my opinion, it was a bit sloppy in the way the diagnosis of toxoplasmosis was confirmed. There was no antibody test that is normally and preferentially done to show the patient is harboring toxoplasmosis in their body. They simply used a brain-imaging study to make the diagnosis.

When those patients in whom there was serologic confirmation of toxoplasmosis infection were taken out of that study, it really loses its statistical power very quickly.

The other study, from Thailand, was never finished. The rate of problems or why they couldn't enroll more patients or other situations was not entirely clear, but it was never finished. So it never reached the point where any statistical power was available. So there has been attempts to do this. I don't remember when the Thai study was published, though. It may have been after 2000.

Q. So just to be crystal clear, the two ideal forms of evidence to support the guidelines are randomized clinical trials or peer-reviewed studies, and you're only aware of two such studies since 1990, correct?

A. Correct.

Q. And both of those results, despite the limitations that you

just described, revealed no significant difference between treatment of active toxoplasmosis between Bactrim and Daraprim, correct?

A. I think the best way -- that was the conclusion of the authors, yes. That was the conclusion of the authors.

Q. And there have been no other clinical randomized trials or peer-reviewed studies on this topic since 1990 despite those two, correct?

A. I don't believe so for active toxoplasmosis in the brain.

MR. McCONNELL: Thank you.

No further questions, your Honor.

THE COURT: There was a series of questions, Doctor, about survival rates, and I'm not sure I understand the import of those questions entirely. I'm sure counsel will enlighten me down the road.

But with respect to an HIV population, particularly before the antiviral drugs were introduced in, I think you said, 1996 --

THE WITNESS: Correct.

THE COURT: -- what can you say about survival rates when a patient also has active toxoplasmosis?

THE WITNESS: Active toxoplasmosis is a high mortality disease. The estimates of around 30 to maybe 40 percent death either because of lack of treatment success or because of recurrence after the initial treatment, and death due to that

was very common during those days.

I can tell you that what we as physicians were simply doing was postponing the inevitable in terms of trying to treat several, oftentimes at one time, in one patient, opportunistic infection. And toxoplasmosis was always one of the worst because it involves probably the most important organ in the body — the brain. And, therefore, survival really depended upon promptness of diagnosis, promptness of institution of treatment, completion of treatment, which went very easily six to eight weeks, and then in order to ensure some degree of latency of the organism, promptly putting the patient on the secondary prophylactic or maintenance regimen.

What we were finding, of course, was an ever-declining immune system and trying to use pharmacologic coverage as a way to make up for that ever-declining immune system.

Sometimes that worked very well, sometimes it didn't. I would just say in my experience, the average lifespan for a person who was diagnosed with toxoplasmosis before 1996 was no greater than 12 to 18 months.

THE COURT: And, typically, for that patient population, were they suffering solely from active toxoplasmosis, or were there a variety of infections that had to be addressed at the same time?

THE WITNESS: At the immunological deficit level that toxoplasmosis occurs, which means that they have -- and this

has been very clearly worked out by many studies — at CB4 positive T cell count, an immune cell count of 100 or less, when the normal range is between 500 to 1500, at a T cell count less than 100, the person is susceptible to many opportunistic infections — pneumocystis pneumonia, cryptococcal meningitis, candidal infections throughout the esophagus and other parts of the gastrointestinal tract, cryptosporidiosis causing horrible diarrhea.

So what oftentimes we were dealing with was a series, and sometimes even concurrencies of these infections, which made treatment oftentimes difficult.

So this is something that I look back on in my memory as being a very difficult time of watching persons die of diseases that were kind of converging on them, and the ability to treat or prevent all of them was a great difficult chore.

THE COURT: Because of that, is it difficult to say what a survival rate is due to one infection, when there are multiple attacks on the system?

THE WITNESS: Exactly. I think you are perceiving this very clearly, in the fact that mortality due to a single opportunistic infection was very hard during that period of time to really delineate. We could only say a patient would die with a disease, not necessarily of a disease. It oftentimes was the last opportunistic infection we diagnosed that became the cause of the disease, or at least a

contributing cause, but there were probably many infections, some of which we didn't even diagnose.

THE COURT: So let's take 1996 and the miracle with which these patients and the physicians treating them were given.

What can you say on the same topic of survival rates with patients who have active toxoplasmosis after 1996?

THE WITNESS: It was really almost like night and day.

Number one, one of the most important impacts of successful anti-retroviral therapy was reconstitution of the immune system and T cell counts that were always going down reversed and starting going up.

We learned very quickly that if a patient had a T cell count less than 100 and was at risk for toxoplasmosis, and often had to be on prophylaxis primary prevention, as soon as that T cell count got over 150, we could stop the prophylaxis, and the cases of toxo really diminished very quickly because of that, because of the healing power that the anti-retroviral medications had of reconstituting the immune system that was really the big problem, is why all of these opportunistic infections were occurring. So survival was remarkably different, and the number of cases of toxoplasmosis also decreased remarkably to those persons who were afforded the availability of the anti-retroviral medication.

THE COURT: Thank you.

So, based on my questions of Dr. Hardy, do counsel have any additional questions?

MS. PEAY: No further questions for plaintiffs, your Honor.

MR. McCONNELL: Sean McConnell, your Honor, for defendant, Shkreli.

No further questions. Thank you.

THE COURT: Thank you.

So, Doctor, I can't let you leave the stand without thanking you for the care you've given to your patients and those who love them, and so thank you.

(Witness excused)

THE COURT: Next witness.

MR. MEIER: Your Honor, Markus Meier, on behalf of the FTC.

We'd call -- first of all, let me introduce the attorney from the FTC who will be handling this. It is Attorney Black, and the witness is Christina Ghorban.

THE COURT: Is it Ms. Ghorban?

THE WITNESS: Yes.

CHRISTINA GHORBAN,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows. Please be seated you may remove your mask you may stated your full name.?

THE WITNESS: Christina Ghorban.

THE COURT: Can you spell your first and last name, please?

THE WITNESS: C-h-r-i-s-t-i-n-a G-h-o-r-b-a-n.

THE COURT: Counsel.

MX. BLACK: Thank you, your Honor, and good afternoon.

Armine Black, on behalf of plaintiffs, and good afternoon, Ms. Ghorban.

DIRECT EXAMINATION

BY MX. BLACK:

Q. Ms. Ghorban, let's begin with your professional background and responsibilities when you worked at Vyera.

You worked at Vyera from April 2015 to October 2016, correct?

A. Yes. It was Turing Pharmaceuticals then.

Q. Understood.

And for the clarity of the record, I will refer to Turing and Vyera interchangeably.

Will you understand me to refer to the same company?

A. Yes, I will.

Q. You were Vyera's head of marketing and business analytics when you left the company, correct?

A. Yes.

Q. One of your responsibilities at Vyera was to support commercial assessment of potential drug acquisition targets, correct?

A. Yes.
Q. And one of the drugs you helped to evaluate for acquisition was Daraprim, correct?
A. Yes.
Q. Vyera bought Daraprim in early August of 2015, correct?
A. Yes.
Q. And after Vyera acquired Daraprim, you managed the launch of Daraprim?
A. Yes, along with other people.
Q. In fact, you led all aspects of Daraprim's launch after acquisition, correct?
A. I participated in a lot of the launch activities. I was not the chief commercial officer.
Q. And the chief commercial officer was Nancy Retzlaff?
A. Yes, it was.
Q. And she was your boss?
A. She was my boss, yes.
Q. You reported directly to her?
A. Yes.
Q. And she reported directly to Martin Shkreli?
A. Yes.
Q. Ms. Ghorban, you helped to set up Vyera's Daraprim distribution system, correct?
A. Yes.
Q. You helped to set up Vyera's Daraprim distribution

agreement?
A. Yes.
Q. You helped to manage the distribution agreements after they were set up?
A. Yes.
Q. And you tracked where Daraprim's sales went?
A. Yes.
Q. And Ms. Ghorban, outside of Vyera, you have -- or including Vyera, you have to about 20 years of experience in the pharmaceutical industry, correct?
A. Yes.
Q. And you have worked at six different companies over the course of your career?
A. I believe so.
Q. And these were pharmaceutical companies?
A. Yes. There was a brief stint where I was consulting, but, otherwise, yes.
Q. Now, let's talk a little bit about your interactions with Martin Shkreli during your time at Vyera.

Martin Shkreli was Vyera's CEO when you joined the company in April of 2015, correct?
A. Yes.
Q. Did Shkreli interview you for the job?
A. I don't recall.
Q. Martin Shkreli remained the CEO until December of 2015,

when he was arrested, correct?

A. Yes.

Q. So you overlapped with Mr. Shkreli for about nine months?

A. Yes.

Q. And during those nine months, you saw him on a regular basis?

A. Yes.

Q. And how often is a regular basis?

A. Every day, multiple times a day.

Q. You had direct interactions with Martin Shkreli about Daraprim acquisition?

A. Yes.

Q. And you had direct interactions with Martin Shkreli about Daraprim price increase?

A. Yes.

Q. And you had direct interactions with Martin Shkreli about Daraprim distribution?

A. I don't recall if it was directly with Martin at that time or if it was through his team of business development colleagues.

(Continued on next page)

Q. Martin Shkreli asked you about Daraprim distribution channels, correct?
A. After the acquisition or before?
Q. Either.
A. I know we had discussions of the distribution. I would think it would have been before and after. There were a lot of conversations that happened during that period.
Q. Martin Shkreli definitely asked you about Daraprim sales after acquisition?
A. Yes.
Q. And you gave Martin Shkreli updates on Daraprim business and the source of the business after acquisition?
A. Yes.
Q. And you took direction from Martin Shkreli about Daraprim business, correct?
A. Yes.
Q. Ms. Ghorban, you mentioned earlier Vyera's business development team. I would like to ask you some questions about that.

The role of Vyera's business development team was to find drug acquisition targets for the company, correct?
A. That was one of their roles. The other one was to ensure the direction for those products that were acquired were carried out by the rest of the organization.
Q. And the directions came from Martin Shkreli?

A. I think directly from him, but also they discussed them in meetings pretty frequently, so overall strategy was decided by that team quite often.

Q. And evaluation of Daraprim acquisition was led by the business development team?

A. Yes.

Q. And Martin Shkreli as well?

A. Yes.

Q. Martin Shkreli directed Vyera's business development team?

A. Yes.

Q. And he directed Vyera's business development team in addition to serving as the CEO of the company?

A. Yes.

Q. Was Michael Smith a member of the business development team?

A. Yes, he was.

Q. He came to Vyera from Retrophin?

A. I believe so.

Q. Patrick Crutcher was a member of the business development team?

A. Yes.

Q. He also came to Vyera from Retrophin?

A. I believe so.

Q. And Edwin Urrutia of the business development team?

A. Yes.

Q. He as well came to Vyera from Retrophin?
A. I don't know. I don't recall where he came from.
Q. And Ron Tilles was a member of the business development team?
A. I don't remember what his role was at that time that we acquired Daraprim.
Q. Did he become a member of the business development team eventually?
A. I don't recall him being a part of that team. I'm not exactly sure what role he played until after Martin left.
Q. After Martin left, Martin Shkreli left, he became the CEO?
A. Yes.
Q. Mr. Tilles joined Vyera from Retrophin as well?
A. I don't know.
Q. Ms. Ghorban, let's briefly discuss Mr. Shkreli's involvement in Vyera after he resigned as the CEO.
A. OK.
Q. You don't recall directly communicating to Martin Shkreli after he resigned as the CEO, correct?
A. No. I had no phone calls or texts with him.
Q. But it is your understanding that Shkreli continued talking to Vyera's business development team after he left as CEO, is that correct?
A. That was my understanding.
Q. And it was your understanding that there was a certain

number of people at Vyera who continued to have a relationship with him after he left as CEO of the company?

A. Yes. I was told that.

Q. Who told you that?

A. I believe it was Michael Smith told me that. I believe Edwin told me that as well.

THE COURT: Edwin --

THE WITNESS: Edwin Urrutia. I don't recall who else, but I know that we were hearing -- I was getting requests from people within the organization for information and data, updates on the path of Martin.

Q. You were getting requests about Daraprim business?

MR. CASEY: Your Honor. I am going to object. These questions are eliciting hearsay.

THE COURT: Overruled.

Q. I'll reask the question, Ms. Ghorban.

You said earlier that you were getting requests about data?

A. Yes.

Q. Were those requests concerning Daraprim business?

A. Yes.

Q. And Vyera's business more generally?

A. It was primarily focused on Daraprim because that was the entire business at that time.

THE COURT: Counsel, I think you might need to move

that mic.

THE WITNESS: Is it me?

THE COURT: I don't think it's the witness. I think it's counsel.

MS. BLACK: Thank you, your Honor. Let me know if issues continue.

Q. What was the nature of the request that you were getting about Daraprim business?

A. I don't recall offhand, but we were giving regular reports about sales, regular reports about contracting. There were just sort of general business reports that you would report in any company.

Q. Those were the reports that you would present or were those reports that were given to you?

A. No. They were reports that my team created.

Q. Those reports were presented to Martin Shkreli?

A. I gave them to whoever asked them, asked for them, so it could have been Nancy, it could have been Michael Smith. It could have been any number of people on the business development team.

Q. And the members of the business development team continued talking to Martin Shkreli after he left as CEO?

A. That was my understanding, yes.

Q. Now, let's focus on the Daraprim acquisition. Vyera's evaluation of Daraprim acquisition occurred in the spring,

summer of 2015?
A. Yes, I believe so.
Q. And you helped Martin Shkreli and the business development team to evaluate drug Daraprim as a possible acquisition target?
A. I helped, but it was not in a primary role.
Q. You participated in a lot of discussions about Daraprim acquisition?
A. Some, yes.
Q. I believe you testified in your deposition that you participated in a lot of discussions about Daraprim, correct?
A. Yeah. There were a lot of discussions and it was definitely an important topic.
Q. These discussions were led by the business development team?
A. Yes, they were.
Q. And Martin Shkreli?
A. Yes.
Q. As part of the Daraprim acquisition you helped to evaluate the opportunities and challenges with acquiring Daraprim?
A. Yes, I did.
Q. You conducted market research --
A. Yes.
Q. -- into Daraprim?
A. Yes.

Q. And you presented your findings to Mr. Shkreli?
A. I don't recall if I presented them directly to him, but I did do a report on it. I think we included the findings and some of the internal documents.
Q. You presented your findings to Nancy Retzlaff?
A. Yes.
Q. And the business development team?
A. I don't recall if we presented them directly to them, but they had -- I know I sent them the report.
Q. You sent your findings to the business development team?
A. I believe so.
Q. Now, let's focus on your discussions about Daraprim price increase after acquisition.

Martin Shkreli was involved with the Daraprim price increase, correct?
A. He led the strategy behind it.
Q. And you discussed the Daraprim price increase with Martin Shkreli?
A. Yes.
Q. And the business development team?
A. Yes.
Q. And your boss, Nancy Retzlaff?
A. Yes.
Q. How many discussions did you have with Martin Shkreli about the price increase?

A. Multiple. I don't recall how many. It definitely came up multiple times in multiple different meetings.
Q. More than ten meetings?
A. I don't think I was included in more than ten meetings, but definitely every meeting that we had on Daraprim included a conversation around the price increase.
Q. Those meetings occurred in the spring and summer of 2015?
A. Yes. I was primarily involved towards the end of that period.
Q. And in these discussions you raised the issue that there could be a pushback to the price increase from Daraprim patients?
A. Yes, I did.
Q. Martin Shkreli did not believe you?
A. He said I didn't know what I was talking about.
Q. And he knew what he was talking about?
A. I don't know what he thought.
Q. Martin Shkreli told you that there will not be any reactions to the price increase from Daraprim patients, correct?
A. He said there wouldn't be any reaction, right.
Q. Shkreli ultimately made the decision to raise the price of Daraprim?
A. Yes.
Q. And the price increase was about 4,000 percent?

A. Yes.
Q. You haven't seen a price increase of this magnitude in your 20 years of experience in the pharmaceutical industry, correct?
A. I have not.
Q. It was unprecedented?
A. I can't say that it was unprecedented. I haven't seen a price increase that high in my experience.
MS. BLACK: Ms. Flint, could you please put Government Exhibit 1228 on the screen.
Q. Ms. Ghorban, I'll be sharing some documents with you today. They will appear on your screen. I'll ask some questions about them.
Is the document on your screen right now?
A. Yes.
Q. Ms. Ghorban, have you seen the document marked as GX-1228 before?
A. Yes.
Q. And it is an April 2015 chat between you and Michael Smith, correct?
A. Yes.
Q. And Michael Smith was a member of the business development team?
A. Yes.
MS. BLACK: Your Honor, I move to admit GX-1228 in evidence.

THE COURT: Received.

(Government Exhibit 1228 received in evidence)

Q. Ms. Ghorban, this is an April 2015 conversation between you and Michael Smith, correct?

A. Yes.

Q. And this occurred about four months before Vyera bought Daraprim?

A. Yes.

Q. I'd like to direct your attention to the line that starts with Tina Ghorban, 9:14 a.m.

A. Yes.

Q. The second sentence says: Martin also asked us to think about possible commercial challenges to selling Daraprim specifically since that's more near term, and I just wanted to understand the pricing, both current and planned.

Do you see that?

A. Yes, I see that.

Q. Martin is Martin Shkreli?

A. Yes.

Q. Does us refer to you and Michael Smith here?

A. I think this refers to us as the commercial team, so myself and Nancy Retzlaff.

Q. Commercial challenges refers to challenges due to the planned price increase?

A. I don't think it was specific to price increase. I think

it was just any commercial challenges of selling the product.
Q. Including distribution challenges?
A. I don't think I understood anything about the distribution process at that point, and I hadn't previously worked on distribution, so I wouldn't have considered it.
Q. I'd like to direct your attention now to the line that says Tina Ghorban, 9:20 a.m.
A. Um-hum.
Q. You see where it says: Just thinking that doctors tend to be less price sensitive, but the HIV patient advocacy groups are really well-organized and very sensitive to issues that disproportionately affect their members. There could be backlash to such a significant price increase.

Do you see that?

A. Yes, I do.
Q. Are you referring to a significant price increase of Daraprim?
A. I can't recall if this was about -- I think we were looking at sulphadiazine as well, but I think it was about Daraprim.
Q. Backlash refers to backlash from patient advocacy groups?
A. Yes.
Q. Staying with the same message, but focusing on the last line where it says: Seems there are no alternatives, though. So maybe it's a moot point. Do you see that?
A. Yes, I do.

Q. You are saying that there are no alternatives to Daraprim for the treatment of toxoplasmosis here?
A. I think that's what I'm alluding to and this, again, was very early on in the analysis. So we hadn't quite fully understood the commercial -- the competitive framework.
Q. And you reached this conclusion about there being no alternatives based on your market research in advance of Daraprim acquisition?
A. Again, I think it was very early on, so based on the quick look at the market, I think that's what I came to, was this was -- there were not a lot of alternatives.
Q. Did this remain your conclusion about there being no alternatives as you continued working with Daraprim after acquisition?
A. The conclusion that we came to was that Daraprim plus sulphadiazine was the gold standard for the treatment of active toxoplasmosis. But there were alternatives, but less desirable alternatives.
MS. BLACK: We can take down this exhibit. Thank you, Phoebe.
Q. Ms. Ghorban, now let's talk about Daraprim distribution.
A. OK.
Q. To set some definitions first, are you familiar with the term open distribution?
A. I am now.

Q. Open distribution generally means that a drug is broadly distributed through multiple full-line distributors and available for purchase through retail pharmacies?

A. Yes.

Q. And closed distribution, in contrast, generally means that a drug is distributed through a more limited number of distributors and is not available at retail pharmacist?

A. Yes.

THE COURT: Sorry, counsel. I lost track of time here. I'm very sorry. We are going to take our luncheon recess. We will start back at 2:00.

Enjoy your lunch. Thank you.

(Luncheon recess)

AFTERNOON SESSION

2:00 P.M.

(Trial resumed; in open court)

THE COURT: The witness may retake the stand.

Counsel.

MX. BLACK: Yes, your Honor.

CHRISTINA GHORBAN, resumed.

DIRECT EXAMINATION CONTINUED

BY MX. BLACK:

Q. All right. Welcome back.

A. Thank you.

Q. Right before the recess, we started talking about open and closed distribution.

Do you remember that?

A. Yes.

Q. And just to briefly recap, open distribution generally means that a drug is broadly distributed through multiple full-line distributors, correct?

A. Yes.

Q. And available through retail pharmacies?

A. Yes.

Q. And closed distribution generally means that a drug is distributed through a more limited number of distributors, correct?

A. Yes.

Q. And is not available at retail pharmacies?
A. That's not a term that I would say is common in the pharmaceutical industry. I think we usually typically say a product is in retail or it's in specialty. Those are the terms that I've seen more frequently.
Q. For the first 60 years after Daraprim launched, it was an open distribution, correct?
MR. CASEY: Your Honor, I object. I don't believe that counsel has established the necessary adversity of this witness to be asking leading questions.
THE COURT: Overruled.
THE WITNESS: Would you repeat the question?
BY MX. BLACK:
Q. Yes.
For the first 60 years after Daraprim launched, it was in open distribution, correct?
A. I don't know. I assume that -- I know it was in retail at some point before Vyera acquired it.
Q. During your time at Vyera, Daraprim was distributed through a closed distribution system, correct?
A. It was distributed through specialty pharmacies and institutions.
Q. And that kind of distribution is more closed than the open distribution, which is defined?
A. Closed, meaning -- what do you mean when you say "closed"?

THE COURT: It's more closed than retail distribution?

THE WITNESS: It's limited. Yeah, there's more -- the distribution is limited to a fewer number of outlets.

BY MX. BLACK:

Q. And limited distribution is sometimes referred to as closed distribution?

A. Vyera was the only place I've ever heard it referred to it as that way. I had never heard that term, and continue to not hear that term. It's specialty versus retail mostly, in my experience.

Q. But at Vyera, you heard the term "closed distribution" used?

A. I did hear the term there.

Q. And you heard the business development team using that term?

A. I did.

Q. And Martin Shkreli using that term?

A. I don't recall if I ever heard him say specifically closed distribution, but I think it was on emails, and definitely he was part of those chains.

Q. So since Vyera, the company, referred to Daraprim distribution as closed, I will refer to it as such for this trial.

A. Okay.

Q. Is that okay?

So Daraprim wasn't available for purchase in retail pharmacies after Vyera acquired the product, correct?

A. Correct.

Q. And it was only available through specialty pharmacies?

A. It was available through specialty pharmacies and institutions.

Q. Such as hospitals?

A. Hospitals. I believe we opened it up to clinics related to hospitals, ADAPs. We had stock in Walgreens specialty pharmacy stores that were located in institutions.

THE COURT: What does the term "ADAP" mean?

THE WITNESS: It's AIDS Drug Assistance Program.

BY MX. BLACK:

Q. And there were no safety issues with Daraprim, as far as you know, that required a change from open to closed distribution system, correct?

A. Not as far as I know.

Q. Let's focus, Ms. Ghorban, on your conversations with Martin Shkreli and the business development team about the use of closed distribution system for Daraprim.

You have heard Martin Shkreli say that closed distribution can make it harder for generics to obtain the branded drug, correct?

A. I don't recall him specifically saying it at any point, but -- I just don't recall. I know it was a conversation that

we had multiple times in many different situations before Vyera acquired Daraprim and after.

Q. You testified in your deposition that Martin Shkreli mentioned using closed distribution to prevent generics to obtain Daraprim?

A. Again, I don't recall specifically. We had a lot of conversations, there were a lot of emails about it. I think I was forwarded an email. So I just don't recall, to be honest, a specific instance of him exactly saying that. But it was a conversation that we had many, many times in multiple meetings, with all -- with him in those meetings, with the BD business development team in those meetings.

Q. In June of 2015, Martin Shkreli and the business development team discussed with you the strategy of using a closed distribution system to prevent generic entry, correct?

A. I think we started getting emails about it, and we started having discussions about it then.

Q. So the answer is yes?

A. Yes.

Q. When you say we started getting questions about it, are you referring to yourself and Nancy Retzlaff?

A. Yes, and the broader commercial team at that time.

Q. Who else was in the commercial team?

A. I think we had a head of sales on that team by that point, we had a small sales team, but it would have been the sales

leadership, myself, Nancy, perhaps some other marketing people that may have been involved.

Q. Could you name names?

A. It was still a small group. I can't remember exactly at what point we hired certain people, but there were multiple people involved.

Q. And in those meetings you just mentioned, Martin Shkreli and the business development team discussed using closed distribution to make it harder for generics to acquire Daraprim, correct?

A. Yes.

Q. And generic companies seeking to develop a competing generic Daraprim required Daraprim samples, correct?

A. I believe so.

Q. And Daraprim samples are necessary to show to the FDA that the generic is bioequivalent to Daraprim?

A. Yes, they have to conduct studies that compare their product to the listed product to be able to show equivalence.

Q. And the business development team told you that they had an interest in not making it easy for a generic company to acquire Daraprim?

A. Yes.

Q. And they had this interest because a generic launching with a competing product would have a dramatic impact on Vyera's revenue, correct?

A. Yes.
Q. And a generic launch would, in fact, dramatically decrease Vyera's revenue?
A. Yes.
Q. It would decimate it?
A. Yes.
Q. Daraprim was Vyera's primary source of revenue during your time, correct?
A. Yes.
Q. So it was one of the objectives of the business development team and Martin Shkreli to impede generic entry?
A. Yes.
Q. And you have heard discussions -- you have had discussions with the business development team about using closed distribution to make it harder for generics to get access to Daraprim?
A. Yes.
Q. And, in fact, multiple people at Vyera discussed that objective with you at multiple times?
A. I would say primarily the business development team.
Q. So the business development team discussed that objective with you on multiple occasions?
A. Yes.
Q. And using a closed distribution to impede generics was very much a topic of discussion at the time of the Daraprim

acquisition?
A. Yes.
Q. And given the importance of Daraprim to the company's revenue, every single person from business development was involved, at one point or another, in Daraprim distribution contracts, correct?
A. I don't know if every single person on the business development team was involved in contracts. I would say the three we mentioned — Chris -- sorry, Mike Smith, Edwin Urrutia, Patrick Crutcher — were the ones that I worked most closely with. I think there were a couple of other people on that team that I didn't have as much contact with.
Q. And Daraprim distribution contracts were incredibly important documents, correct?
A. Yes.
Q. Because they enabled Vyera to sell product?
A. Yes.
Q. And generate sales?
A. Generate revenue, yes.
Q. And every person who was interested, which included Martin Shkreli and his business development team, reviewed distribution contracts?
A. I don't know that every single person reviewed the distribution contracts. They're fairly lengthy, there's a lot of legal terminology. Legal definitely reviewed the

distribution contracts. I recall sitting in with Mike Smith and going pretty thoroughly through some of the contracts. I shared a lot of contracts, but I don't know that every single person reviewed them.

Q. Why don't we take a look at your deposition.

MX. BLACK: Phoebe, could you bring up page 226.

Q. Ms. Ghorban, do you have it on your screen?

A. Yes.

Q. Do you see, starting on line 4:

"Q. Do you remember Mr. Shkreli being involved in these distribution contracts in any way that wasn't hands-on like the manner you described?"

And then starting on line 9:

"A. I don't remember -- I don't remember specifics. I know that they were incredibly important documents because it enabled us to sell the product and distribute the product and would generate sales. So I know that every person who was interested, which was him and his team and obviously the commercial leadership, would have reviewed it."

Do you see that?

A. I see that.

MR. CASEY: Your Honor, I object to the witness using this for impeachment. I don't think it's proper impeachment when it hasn't been established as to whether the witness testified contrary to the deposition.

THE COURT: Sustained. Stricken.

MX. BLACK: Could I use it for refreshment?

THE COURT: Certainly, but you need to lay a foundation.

BY MX. BLACK:

Q. Ms. Ghorban, you testified earlier that you did not remember every single person reviewing Daraprim distribution contracts, correct?

A. Correct.

Q. Would looking at your deposition transcript refresh your memory?

MR. CASEY: Objection, your Honor. She's trying to impeach the witness --

THE COURT: Sustained. Sustained.

MX. BLACK: Okay. I'll move on.

BY MX. BLACK:

Q. Ms. Ghorban, let's take a look at one other document.

MX. BLACK: Phoebe, could you bring up GX 1207.

Q. Do you see it on your screen?

A. I see that.

Q. And GX 1207 is an April 2015 email chain from Michael Smith to you and Nancy Retzlaff?

A. Yes, I see it.

Q. And the subject line is sulfadiazine?

A. Yes.

MX. BLACK: Your Honor, I move Exhibit 1207 in evidence.

THE COURT: Received.

(Government's Exhibit 1207 received in evidence)

BY MX. BLACK:

Q. Ms. Ghorban, let's look at the bottom email on this page from Michael Smith.

And Michael Smith was on the business development team?

A. Yes.

Q. The email says, "Another item to keep on your radar is sulfadiazine. It is a sole-source (U.S. only, generic ex U.S.) infectious disease product from Sandoz indicated for toxoplasmosis. This would be the classic closed distribution play. We think it could do more than 250 million per annum. I have attached a short dec and the model for some quick background."

Do you see that?

A. I do.

Q. I think you mentioned already earlier that sulfadiazine was another product that Vyera was considering acquiring around spring/summer of 2015?

A. Yes.

Q. And sulfadiazine was a sole-source product in the United States?

A. That's what he's telling me in this email.
Q. And "sole source" means that there is only one company producing that product with that API?
A. I don't know about the API part, but it's the way that I interpret it as, it's one company selling the product.
Q. And it means that it doesn't have a generic competitor?
A. I don't know if this is a brand, so I can't say that it has a generic competitor or not. If it's a generic, then it's a generic, but it just tells me that this is -- there's only one company selling this product at the moment. It could be brand or generic.
Q. Got it.
So, in this case, it would mean it was the only generic on the market?
A. It was the only product -- the only product of that molecule on the market.
Q. And Michael Smith is using the term "classic closed distribution play," correct?
A. Yes, that's the term he's using.
Q. And that term refers to the concept that you could use closed distribution to make it more difficult for generics to get reference-listed drugs for bioequivalence studies, correct?
A. I know that now. I didn't know that at the time. I didn't know what he meant by that. I had never heard that term before.

Q. But you understand it to mean that now?
A. Yes.
Q. And using closed distribution -- strike that.
So Vyera was considering a closed distribution strategy for sulfadiazine to impede generic -- another generic competitor?
A. Yeah, I think that's what he meant.
Q. So let's look at the top email in the same document, GX 1207. And the second paragraph, the second full paragraph, says -- it starts with, "We are also now in the process" -- so it says, "We are also now in the process of bidding for Daraprim (pyrimethamine) as a sole-source product from Impax Labs. Pyrimethamine plus sulfadiazine combo therapy is the gold standard for toxoplasmosis. I would build a similar dec specific to Daraprim."
Do you see that?
A. Yes, I do.
Q. So this email was sent on April 29, 2015, correct?
A. Yes.
Q. And it was when around the time business development team was evaluating Daraprim as a potential acquisition target?
A. Yes.
Q. And pyrimethamine refers to the active ingredient in Daraprim?
A. Yes. It's the generic name for it.

Q. And a sole-source product means that -- that refers to Daraprim not having pyrimethamine competitors in the United States?

A. Correct.

Q. And it mattered to the business development team that Daraprim didn't have generic competitors, correct?

A. Yes.

Q. And why did it matter?

A. There was an increased opportunity for revenue.

MX. BLACK: Thanks, Phoebe. You can take it down.

Q. Let's look at another document.

MX. BLACK: Phoebe, could you bring up GX 1303 -- sorry, sorry, 1302.

Q. Ms. Ghorban, do you have GX 1302 on your screen?

A. I do.

MX. BLACK: Your Honor, GX 1302 is already in evidence as one of the documents on plaintiffs' first list of exhibits to be admitted in GX 9001.

Q. So, Ms. Ghorban, GX 1302 is a June 2015 email chain from Nancy Retzlaff, your boss and chief commercial officer at the time, correct?

A. Yes.

Q. The subject line is Project DART.

Do you see that?

A. Yes.

Q. And Project DART is the code name for Vyera's plan to buy Daraprim?

A. Yes.

Q. Now let's take a look at the bottom email on the first page. And it carries over to the next page, but we can start on the first page.

It says, "Tina, Rick: Martin shared an update today re Project DART (Daraprim) at the leadership team today. Based on today's discussions, he anticipates roughly a two-week timeline until the deal potentially closes. As you're both aware, the priority work stream is to ensure the product is moved into closed distribution as swiftly as possible in order to minimize exposure."

Do you see that?

A. I do.

Q. So this email is from June 9, 2015?

A. Yes.

Q. And that was two months before Vyera acquired Daraprim?

A. Yes.

Q. And "Martin" in this email refers to Martin Shkreli?

A. Yes.

Q. "Priority work stream' refers to the highest priority tasks?

A. Yes.

Q. Which was said by Martin Shkreli?

A. I'm assuming because he said it's an update and based on other conversations.

Q. Do you have any reason to doubt that it was said by Martin Shkreli?

A. No.

Q. Where it says "to ensure the product is moved into closed distribution," "the product" refers to Daraprim?

A. Yes.

Q. So the highest priority task said by Martin Shkreli was moving Daraprim into a closed distribution system after acquisition?

A. That's what she's saying, yes.

Q. And that was true?

A. It was one of the -- it was one of the priorities, yes. It was a priority for the business development team.

Q. And Martin Shkreli?

A. Yes.

Q. And it was necessary to do it as swiftly as possible to minimize exposure to generic competitors being able to access Daraprim?

A. Yes.

MX. BLACK: Thanks, Phoebe. You can take it down.

Q. Ms. Ghorban, let's talk now a little bit about IQVIA data.

A. Okay.

Q. IQVIA is a standard data source in the pharmaceutical

industry, correct?
A. Yes, it is.
Q. And it used to be called IMS, correct?
A. Correct.
Q. IQVIA collects and reports a variety of pharmaceutical data?
A. Yes.
Q. It captures prescribing data?
A. Yes.
Q. Sales data?
A. Yes.
Q. Data around patients' age groups?
A. Yes.
Q. Prescribers' specialties?
A. Yes.
Q. And prescribers' age groups?
A. Yes. And a lot more stuff. There's a lot more data in there than just those.
Q. It's a rich dataset?
A. Yes.
Q. And IQVIA data is a standard data source that companies and analysts will look at to understand the dynamics of markets and products?
A. Yes.
Q. In your experience, IQVIA data is always part of the

assessment in decisions to acquire a product, correct?
A. It's always a starting point.
Q. You always check IQVIA data to assess products for drug acquisition?
A. Yes.
Q. And you always check IQVIA data to assess products for drug development?
A. Yes. Or Symphony. Symphony is another data source.
Q. So Symphony is another pharmaceutical data aggregator?
A. Yes.
Q. And IQVIA data isn't free, correct?
A. No. As a pharmaceutical company, you have to pay for a subscription.
Q. And Vyera, in fact, had paid for a subscription to IQVIA data when you were at the company?
A. Yes.
Q. And you looked at IQVIA data to assess Daraprim for acquisition?
A. I know I would have checked IQVIA. I don't know if there was -- it's a small product -- it was a small product, so when you have smaller products, the data is not as consistent and is not as reliable, but I would have started there.
Q. So you looked at IQVIA data as a starting point?
A. Yes.
Q. And Vyera's business development team also looked at IQVIA

data?
A. I think they used an epidemiological model, which is patient-based, but I'm sure they would have looked at IQVIA data as well.
Q. For Daraprim?
A. Yeah.
Q. Now, let's discuss the direction you received from the business development team about blocking Daraprim data.
So after the Daraprim acquisition, the business development team asked you to talk to Daraprim distributors about not reporting Daraprim distribution data to IQVIA and other data aggregators, correct?
A. Yes.
Q. And other data aggregators would have included Symphony?
A. Yes.
Q. And one of the reasons that the business development team asked you to talk to Daraprim distributors about this issue was so that data-reporting companies would show less in terms of volume and sales for Daraprim?
A. Yes.
Q. And that mattered because if sales looked like they were going down, there would be less interest from other companies to develop generic Daraprim?
A. That was their belief.
Q. And data blocking was part of the business

development team's strategy to discourage generic entry?
A. Yes.
Q. And it was part of Martin Shkreli's strategy?
A. Yes.
Q. And this strategy was communicated to you on multiple occasions?
A. Yes.
Q. You had multiple conversations with the business development team about data blocking?
A. Yes.
Q. And Martin Shkreli was involved in those conversations?
A. I think we started talking about data blocking after the acquisition, so I was mostly dealing with the BD team directly at that point about some of the details, but the BD team talked to him on a regular basis, and I know we had bigger discussions about it.
Q. And you know, through the business development team, that Shkreli requested that IQVIA data -- sorry, that IQVIA not have their Daraprim data?
A. Yes. They actually asked me to track the data in IQVIA to see if it was going down.
Q. And Shkreli made that request, right, that IQVIA not have Daraprim data?
A. Yes.
Q. Now, let's talk a little bit about your conversations with

Daraprim distributors about blocking Daraprim data.

MX. BLACK: Phoebe, could you bring up GX 1556.

Q. So GX 1556 is an August 2015 email chain from Michael Smith, a member of the business development team, correct?

A. Yes.

Q. And it is to you and Nancy Retzlaff?

A. Yes.

Q. And the subject line is, "Tell Walgreens/ICS We Don't Want Them Reporting To IMS Or Any Other Databases."

Do you see that?

A. Yes.

MX. BLACK: Your Honor, I move to admit Exhibit GX 1556 in evidence.

THE COURT: Received.

(Government's Exhibit 1556 received in evidence)

BY MX. BLACK:

Q. Ms. Ghorban, let's take a look at the bottom email first. It is dated August 10, 2015?

A. Yes.

Q. So it was three days after Vyera bought Daraprim?

A. I don't recall the exact date, but it was early August that the acquisition was complete.

Q. So it was shortly after?

A. I think so.

Q. And the subject is, "Tell Walgreens/ICS We Don't Want Them

Reporting To IMS Or Any Other Databases."

Do you see that?

A. Yes.

Q. Walgreens and ICS were the only Daraprim distributors at the time, correct?

A. Yes.

Q. And "we" in the subject line refers to the business development team?

A. I don't know who he's referring to at that point. "We" -- I would think it would be business development, but I can't, for sure, say.

Q. And "reporting" refers to reporting Daraprim distribution data?

A. Daraprim prescription data and sales data.

Q. And that's Daraprim prescription and sales data that distributors own?

A. I'm sorry, hold on. It would be -- yeah, for Walgreens, it would be the prescription data, and for ICS, it would be the sales data.

Q. And they owned the data?

A. They collect the data because they distribute the product.

Q. But it is their data to report or not to IQVIA?

A. I don't know if it's their data. It's kind of the company's data because they report the data back to the company, but, ultimately, it's their decision who they report

to, who they report the data to.
Q. So they ultimately decide whether or not to report the data?
A. Yes.
Q. Pending any agreement with the manufacturer?
A. Yes.
Q. And other databases in the subject line refers to data aggregators such as Symphony?
A. Yes.
Q. So, shortly after the Daraprim acquisition, Michael Smith asked you to tell Daraprim distributors that Vyera does not want them reporting Daraprim sales and prescription data to IQVIA and other data aggregators, correct?
A. Yes.
Q. Now, let's take a look at your response to the email.

So you reply: "We are talking to both this morning, so will mention it again."
A. Yes.
Q. And "we" refers to you and Nancy Retzlaff?
A. I think it was myself and Nancy. Mike could have been on the phone. I'm not exactly sure who it would have been. There were some other people that were working through the agreements, I believe, and I didn't have any experience in this, so I needed somebody else to help with the process.
Q. And the "Mike" you mentioned, that's Michael Smith?

A. Mike Smith, yeah.
Q. So you planned to talk to Walgreens and ICS about data blocking?
A. We were talking to them about the process of reassigning, I think, the contracts and how we set up a vendor relationship with both of them. So I think, in the context of this email, I was saying we're already talking to them, so we'll mention it again in that conversation.
Q. So you're saying that you will mention data blocking of Daraprim data again to ICS and Walgreens?
A. Yes, in that meeting we already set up.
Q. And you had discussions with Walgreens and ICS about data blocking of Daraprim data before this email?
A. I think we had -- I think we had mentioned it to them. The context was trying to reassign contracts, establish vendor relationship, make sure that there was no disruption in supply. So this was a component of those discussions. It wasn't a priority for the commercial team, nor was it an objective to have a conversation; it was part of the larger discussions.
Q. That you had at the direction of the business development team?
A. The conversation about the databases and the data blocking was at the direction of the business development team. The other conversations were to ensure supply wasn't disrupted.
MX. BLACK: Thanks, Phoebe. You can take it down.

Q. Let's take a look at another document.

MX. BLACK: Phoebe, could you bring up GX 1289.

Q. So GX 1289 is an August 2015 email from you to Nancy Retzlaff, cc'ing Michael Smith?

A. Yes.

Q. And the subject line is: "Update On Distribution Progress and Additional Questions"?

A. Yes.

MX. BLACK: Your Honor, I move to admit GX 1289 in evidence.

THE COURT: Received.

(Government's Exhibit 1289 received in evidence)

BY MX. BLACK:

Q. So, in this email, Ms. Ghorban, you followed up on Michael Smith's data blocking request that we just saw and are now updating Nancy Retzlaff and Michael Smith on outstanding items?

A. Yeah. This is just a general follow-up, and the data blocking is part of that.

Q. And I'd like to focus on the data blocking aspect.

Let's take a look under the heading "Walgreens Progress." And I'd like to focus on the fourth bullet. It says, "Confirmed that they do not disclose Daraprim sales/Rxs to any data reporting company. This was in the original contract with Impax."

A. Yes.

Q. Do you see that?

And "RXs" refers to prescriptions?

A. Yes.

Q. So you talked to Walgreens again?

A. Yes.

Q. And you told them that Vyera didn't want Daraprim distribution data to be reported to IQVIA and other data aggregators?

A. Yes.

Q. And Walgreens confirmed that it does not disclose Daraprim data to any data aggregator?

A. Yes. That was the agreement they had with Impax before we acquired it.

Q. And you requested that they continue not reporting Daraprim data --

A. Yes.

Q. -- After Vyera took over?

A. Yes.

Q. And data blocking wasn't actually spelled out in Impax's contract with Walgreens, correct?

A. I don't recall.

Q. You do not know why Impax had Walgreens not report data, correct?

A. No, I do not.

Q. It could have also been done to make generic entry less

attractive?
A. Based on the theory from the business development team at Vyera, potentially, but I don't know for sure why they did it or when they did it.
Q. Fair enough.
Now, let's take a look under the last section, titled "Requests/Questions for ICS."
Focusing on the fifth item, it says, "We need them to agree not to report into any sales databases, such as IMS, Symphony, et cetera."
Do you see that?
A. Yes.
Q. Who does "we" refer to?
A. "We" is the company.
Q. And that includes Martin Shkreli?
A. Yes.
Q. And "them" refers to ICS?
A. Yes.
Q. So Vyera and Martin Shkreli wanted ICS to agree not to report Daraprim data to IQVIA and other data aggregators?
A. Yes.
Q. And you got ICS to agree to this request?
A. I don't remember if that was actually part of the agreement. I forget if that made it into the contract or not.
Q. Was there an understanding outside a formal contract that

ICS would not report data?

A. Not that I'm aware of. I know I asked -- I requested it of them, but I don't recall if we formalized that and they agreed to it. But based on my experience, they wouldn't just tell us they weren't going to do it and not put it in a contract. It would have had to have made it into some contract, I believe.

MX. BLACK: Phoebe, you can take this one down.

And I'll share yet another exhibit, and it's GX 1307.

Q. Ms. Ghorban, do you see it on your screen?

A. Yes.

Q. So this is a May 2016 email chain between you and --

MX. BLACK: Actually, could you zoom out, Phoebe.

Q. The whole chain -- most of the chain, I guess, is between you and Elizabeth Feldman from ASD?

A. Yes.

Q. And ASD was one of the Daraprim distributors at the time?

A. Yes. We added them.

MX. BLACK: Your Honor, I move to admit GX 1307 in evidence.

THE COURT: Received.

(Government's Exhibit 1307 received in evidence)

BY MX. BLACK:

Q. Now, let's turn to the second page of this email chain, and the second sentence of -- sorry, one second.

Yeah, let's take a look at the March 12, 2016 email

from you to Elizabeth Feldman. In the second sentence of this email, you write, "Also, I'm not sure if I included language regarding not sharing our sales data with third-party data providers, such as IMS. We would like that clause added."

Do you see that?

A. Yes.

Q. So you requested ASD to block Daraprim distribution data from IQVIA, correct?

A. Yes.

Q. And other data aggregators?

A. Yes.

Q. Such as Symphony?

A. Yes.

Q. And that request came from the business development team?

A. Yes.

Q. And the business development team had an interest to block Daraprim data?

A. Yes.

Q. Still looking at the second page of GX 1307, and focusing on Ms. Feldman's response, it says, "Hi Tina. I am meeting with legal today to discuss the amendment. I will also run the data item below by the team. Usually, as a policy from ABC, we don't agree to block data, but will see what I can do."

Do you see that?

A. Yes.

Q. "ABC" here refers to AmerisourceBergen?
A. Yes.
Q. And it's ASD's parent company?
A. Yes.
Q. Now, going to page 1 of this exhibit, GX 1307, you follow up at the bottom of the page. It says, "Hi Liz. Was there any resolution as to whether you could block data to IMS? I know ICS was able to comply with us for that request."
Do you see that?
A. Yes.
Q. So ICS agreed to block Daraprim data per Vyera's request?
A. I guess they did.
Q. So still staying on the first page of GX 1307, Ms. Feldman responds, "Hello Tina. I was able to follow up with our data team at the corporate headquarters. Unfortunately, at this time, we will be unable to block data to IMS. Missing data devalues our relationship with our third-party aggregator partners and our policy to provide a complete picture of the industry."
Do you see that?
A. Yes, I do.
Q. So in May of 2016, ASD did not agree to block its Daraprim sales and prescription data from aggregators?
A. Correct.
Q. Do you know if they eventually agreed to do so?

A. I don't -- not -- I don't believe so when I was there.
Q. So not during your time?
A. No.
Q. So now, still staying with GX 1307, looking at the top email on the page, so you forwarded ASD's response to a number of individuals.

Do you see that?

A. Yes.
Q. And you forwarded it to Nancy Retzlaff?
A. Yes.
Q. Your boss?
A. Yes.
Q. And several members of the business development team?
A. Correct.
Q. One of them is Edwin Urrutia?
A. Yes.
Q. Another one is Patrick Crutcher?
A. Yes.
Q. And the third one is Michael Smith?
A. Yes.
Q. And you forwarded ASD's request to these individuals because they were the ones who asked for this kind of activity regarding data blocking of Daraprim to go on, correct?
A. Correct.

MX. BLACK: Thanks, Phoebe. You can take it down.

I have one last document on data blocking. Phoebe, could you bring up GX 1405.

BY MX. BLACK:

Q. Ms. Ghorban, do you see it on your screen?

A. Yes.

Q. It is a September 2016 email from you with a subject line, "Cardinal Distribution Agreement"?

A. Yes.

MX. BLACK: Your Honor, I move to admit GX 1405 into evidence.

THE COURT: Received.

(Government's Exhibit 1405 received in evidence)

BY MX. BLACK:

Q. So in this email, Ms. Ghorban, you email Crutcher, Patrick Crutcher, and Michael Smith from the business development team?

A. Yes.

Q. And Nancy Retzlaff?

A. Yes.

Q. And you cc Ron Tilles?

A. I cc Ron and Nancy.

Q. Oh, sorry, yes. Thanks for that correction.

And Ron Tilles was the CEO at the time?

A. On September 14th? I don't recall if he was the acting CEO or -- he was playing a leadership role. He may have been still CEO at that time.

Q. So he was either CEO or interim CEO?
A. Yeah, I think so.
Q. Let's take a look at the second sentence, which starts with, "We are expanding distribution to add in Cardinal for inpatient and outpatient hospital pharmacy purchases."
A. Yes.
Q. "This accomplishes two objectives."
And focusing on the second objective there, it says, "The BD group's objective of limiting data availability to IMS: Cardinal Specialty is willing to not report their Daraprim sales to IMS. However, note that their fee for distribution will be 3.05 percent, or 105 basis points, higher than ASD's fee of 2 percent. IMS is a revenue source for them, and the premium is to compensate them for that lost revenue."
Do you see that?
A. Yes, I do.
Q. So the business development group had an objective of limiting data availability to IMS?
A. Yes.
Q. And distributors, such as Cardinal, sell their data to IMS and get paid for it?
A. Yes.
Q. It's a revenue source for them?
A. Correct.
Q. And Cardinal agreed to block Daraprim data, but requested a

data blocking fee in exchange to compensate them for the lost revenue?

A. Correct.

Q. And they requested 3.05 percent of Daraprim's list price?

A. I don't recall what that percentage was. I want to say it's a percentage of the price of the drug, but there may be some other percentages in there.

Q. And ASD agreed to data blocking in September 2016?

A. I don't know. I don't recall if they did. Based on this email -- I'm not sure if that 2 percent, if that's a data blocking percentage or if it's a distribution percentage. I don't recall what that was for.

Q. Okay.

So, now, looking at the last line of this email, it says, "Also, based on your request, we have followed up with all the specialty pharmacies in our network, and they are not willing to withhold our data from IMS as a policy."

Do you see that?

A. Yes.

Q. And "your request," does that refer to the request from Michael Smith and Patrick Crutcher?

A. Yes.

Q. And "all the specialty pharmacies in our network," how many specialty pharmacies are you referring to?

A. By September of 2016, we had expanded beyond just Walgreens

specialty pharmacy to enable patients to access the medication more quickly and access our patient affordability programs, and we were in the process of -- we had moved to a hub network, which is basically a single-source intake, and then the hub does all the insurance work, applies any affordability programs, and then sends it to a specialty pharmacy for dispensing to the patient.

I don't recall the exact number, but we were adding as needed to ensure that patients had access. So I don't -- it was more than three, I think, but we were evaluating and expanding as needed.

Q. So three -- more than five?

A. We were definitely adding a lot at that time, but I don't remember exactly because there was a lot of discussion around which ones would be -- would serve which purpose and where they were located in the country, and which ones were covered by payors. There's a lot of other details.

Q. So at least three pharmacies?

A. I believe so.

Q. So following the business development team's request, you reached out to every entity who had Daraprim distribution data and asked them not to report their data to IQVIA?

A. I believe I reached out to our hub, who was the one that was coordinating the specialty pharmacies, and asked them to reach out to the specialty pharmacies because they had direct

contact with them, I didn't. They managed that network. And I believe that they came back and said, just as a policy, you know, a lot of specialty pharmacies don't do that because it's a source of revenue.

Q. And in addition to the hub, you reached out to ICS?

A. I think ICS was like the year before.

Q. But just like overall --

A. Overall, yes.

Q. -- you reached out to ICS?

A. Yes.

Q. You reached out to Walgreens?

A. Yes.

Q. You reached out to ASD?

A. Yes.

Q. You reached out to Cardinal?

A. Yes.

Q. And you asked them to not report Daraprim sales data to IQVIA?

A. Correct.

Q. So now --

MX. BLACK: We can take this one down.

Q. Let's switch gears a little bit and talk about Daraprim purchase limits during your time at Vyera.

Ms. Ghorban, you were involved in setting up purchase limits on Daraprim orders, correct?

A. I was involved in setting up the process of how hospitals could order from ICS, and part of that was the request to limit the number of bottles they could buy at any one time.

Q. The request came from the business development team?

A. Yes, it did.

Q. Anyone in particular?

A. I don't recall exactly who it was.

MX. BLACK: Phoebe, could you bring up GX 1217.

Q. So GX 1217 is an August 2015 email chain between you and Georgios Tserotas of ICS?

A. Yes.

Q. And ICS was a Daraprim distributor at the time?

A. Yes.

MX. BLACK: Your Honor, I move to admit GX 1217 in evidence.

THE COURT: Received.

(Government's Exhibit 1217 received in evidence)

BY MX. BLACK:

Q. Ms. Ghorban, let's take a look at the bottom email on the first page of GX 1217.

Ms. Ghorban, this email was sent from you?

A. Yes.

Q. To Georgios Tserotas?

A. Georgios, yeah.

Q. Georgios, okay.

Cc'ing Michael Smith?

A. And Nancy, yes.

Q. And Nancy?

And Georgios Tserotas was an ICS representative, right?

A. Yes. He was our customer service contact.

Q. So staying on the first page, this bottom email, let's take a look at the text of your email. It says, "Hi Georgios. Thanks for sending the sales report. We should discuss possibly limiting the maximum number of bottles that we send to any one customer at one time. Our concern is that a generic company could access multiple bottles of our product, perhaps attained through a hospital reselling it or distributing product to surrounding retail pharmacies, and use it to create a generic version."

Do you see that?

A. Yes.

(Continued on next page)

Q. When you say, we should discuss in the first highlighted sentence, are you referring to you and Georgios Tserotas?
A. Yes.
Q. Maximum number of bottles, that refers to bottles of Daraprim?
A. Yes.
Q. Customers refers to Daraprim buyers?
A. Yes.
Q. That includes hospitals buying Daraprim from ICS?
A. Yes.
Q. And specialty pharmacies?
A. At that period of time, in August of 2015, there were no other specialty pharmacies except for Walgreens.
Q. It's referring to maximum number of bottles sold to hospitals?
A. Hospitals, institutions, yeah.
Q. So here Vyera and ICS are discussing the possibility of limiting the maximum number of bottles that ICS can send to hospitals that want to buy Daraprim?
A. Limiting per order.
Q. Looking at the second sentence, our concern is that a generic company could access multiple bottles of our product. Generic companies need multiple bottles of Daraprim for FDA required studies, correct?
A. I don't know how many bottles they need. I'm not familiar

with the process of creating a generic.
Q. They need more than one?
A. I would think, but I don't really have any idea.
Q. When you say our concern, whose concern are you referring to?
A. When I wrote the e-mail, I think it was sort of the royal we, the company concern.
Q. Business development team's concern?
A. It wasn't my concern, so it was coming from -- it was an objective being directed by the business development team.
Q. And Martin Shkreli's concern?
A. Yes.
Q. Business development team and Martin Shkreli were concerned that a generic could buy multiple bottles of Daraprim and use them to create a generic version?
A. Yes.
Q. And you talked to multiple people from the business development team about setting purchase limits to impede generics?
A. Yes.
Q. One of the people was Michael Smith?
A. Yes, definitely Michael Smith.
Q. And you made this purchase limit request at the request of the business development team?
A. Yes. It was definitely part of it was the generic concern.

The other part of it was the redistribution of product to retail pharmacies because at this point they were able to buy the product for a penny a pill. So if they diverted product from say a 340B hospital into sort of the mainstream non-340B patients, it would negatively impact our sales, essentially cannibalize our sales.

Q. Are you aware of any instances of 340B entities reselling it to non-340B buyers?

A. When we tracked hospital sales data, which is a common practice for any pharmaceutical company, we saw that there were aberrations in purchasing habits for more hospitals. They were buying more than they had in the past, in the history that we could see, so we weren't sure if they were using it to treat non-340B patients, which is not appropriate. It's an inappropriate use of the 340B system. Again, it would cannibalize our sales.

Q. You don't actually know if they actually used Daraprim improperly by reselling it --

A. There is not a way to really track it unless you open an investigation, and we weren't in the position to really accuse anybody of anything at that time.

Q. So you tracked Daraprim's sales, you noticed aberrations, but you did not know one way or another if there were actually any instances of abuse from 340B entities?

A. No.

Q. So one of the reasons for Daraprim purchase limits was the objective of the business development team to make it more difficult for generics to get access to Daraprim, correct?

A. Yes.

Q. And the purchase limits that ICS and Vyera agreed on were not in response to any shortages of Daraprim, correct?

A. No.

Q. And purchase limits on multiple bottles of Daraprim make it more difficult for generics to obtain multiple bottles of Daraprim for bioequivalent studies, correct?

A. I have no idea. I don't know.

Q. Let's briefly look at the date of the e-mail. It is August 13, 2015.

A. Yes.

Q. So this was shortly after Vyera bought Daraprim, correct?

A. Yes.

Q. So shortly after Vyera bought Daraprim you reached out to Vyera's Daraprim distributor to agree on purchase limits?

A. Yes.

Q. Now, still staying on the first page of GX-1217, let's take a look at the reply from Georgios Tserotas to you. It says: I agree with this. Based on the sales report you received, what do you think is a reasonable threshold? Five vials? Please let me know and we can implement these limits in our system.

Do you see that?

A. Yeah.
Q. So your authorized distributor, ICS, agreed with Vyera to implement purchase restrictions on Daraprim?
A. Yes.
Q. And ICS in fact established purchase limits on Daraprim as requested, correct?
A. Yes. I don't remember what the limit was. I don't think it was five bottles, but I could be wrong.
Q. But there was a limit implemented?
A. Per purchase order. A customer could order multiple times. They would just split it up by whatever the limit was.
Q. If a customer placed multiple orders one after another, would you flag this series of transactions?
A. I would definitely flag it just to look into it and maybe try to understand, again, if they were -- if it was different than what we had seen them order historically, what was that pattern and, potentially, were they diverting it was my chief concern. Again, I don't know how generics obtained product for creating a generic and doing the research on it. But, yes, I would have flagged it.
Q. So you would flag multiple orders to the business development team, correct? Because they were interested in making it less easy for generics to obtain Daraprim?
A. I don't know that I would flag it to the business development team. I would probably would flag it just as

something to look into further and potentially talk to maybe somebody on the sales team or look at the history and see if it was consistent. I don't know that I even would necessarily say they couldn't sell multiple purchases, but it would be something that would come to my attention, and I would probably explore it further.

Q. And it would come to your attention because one of your roles was to track Daraprim sales, right?

A. Yes.

Q. So if a customer tried to purchase a number of Daraprim bottles exceeding the purchase limit at a given time, then ICS would reach out to Vyera for approval, correct?

A. Yes.

Q. Then Vyera would review the order exceeding the purchase limit and decide whether to approve it or to deny it, correct?

A. Yes.

Q. And if Vyera approved the order, ICS would be able to sell Daraprim in excess of the purchase limit?

A. Yes. I think that was the process we established.

Q. If Vyera denied the order, ICS would not be able to sell Daraprim in excess of the purchase limit?

A. Correct.

Q. And one of the things that Vyera would evaluate in making the decision whether the order seemed -- one of the factors that it would look into to decide whether or not to approve the

order is whether the order was a diversion from prior historical patterns?

A. Yes. That institution's buying patterns before we had acquired -- before Vyera had acquired Daraprim.

Q. Analyzing this kind of diversion from historical appearance was important because the business development team was worried that generics were somehow getting Daraprim through hospitals, correct?

A. I think that was their interest in it and, again, it was the diversion to non-340B patients that potentially would impact revenue, which would affect the company as a whole.

Q. And also diversion to generics?

A. Correct.

Q. And Martin Shkreli was also concerned that Daraprim was being diverted to generics?

A. Yes.

Q. And he directed implementation of restrictions to make it harder for generics to obtain Daraprim, correct?

A. Yes.

Q. Among those restrictions were customer restrictions?

A. Customers -- when you say customers, do you mean certain institutions or just -- having it in a specialty pharmacy and selling directly to institutions, yes.

Q. Another restriction that Martin Shkreli directed to make it harder for generics to obtain Daraprim were purchase limits?

A. I don't recall having a specific conversation with him about purchase limits. I think I mostly worked with Michael Smith on that.

Q. Michael Smith reported to Martin Shkreli?

A. Yes.

Q. The third kind of restriction that we discussed today to impeach generic entry was data blocking, correct?

A. Correct.

Q. That was also implemented at the direction of Martin Shkreli and the business development team?

A. Yes.

Q. To discourage generic entry?

A. Yes.

Q. Thank you, Ms. Ghorban.

MX. BLACK: Your Honor, I pass the witness.

THE COURT: Why don't we take our midafternoon recess. Excuse me just one second here.

Thanks so much, counsel. We will take a five-minute recess.

(Recess)

THE COURT: Put the witness back on the stand. Excuse me just one second.

Counsel, you may begin.

CROSS-EXAMINATION

BY MR. CASEY:

Q. Good afternoon, Ms. Ghorban. My name is Christopher Casey, and I'm here representing the defendant, Martin Shkreli. I have some questions for you this afternoon based upon your testimony earlier.

First, I wanted to just go back to the distribution discussion that you were having earlier regarding the distribution of Daraprim. Do you recall that general topic?

A. Yes.

Q. And counsel indicated that the word closed distribution was used at Vyera and you agreed with that statement. Do you remember that testimony?

A. Yes.

Q. I think you also testified that you understood it as specialty distribution. Did I understand you correctly?

A. What I said was that the more common term in terms of distribution that I've heard is you can either have specialty distribution, meaning it goes through specialty pharmacies, or it goes through retail channels, which is more broad. That's typically the terms that I have heard before then and since then.

Q. I am going to use your term, if it's OK, and call it specialty distribution. You understand that I'm talking about that kind of distribution if I use that term?

A. Yes.

Q. Are there products other than Daraprim that are distributed

through specialty distribution?

A. Yeah.

Q. Have you seen specialty distribution systems at other pharmaceutical companies that you have worked at in your career?

A. Yes.

Q. I'd like to just focus on the specialty distribution systems at Vyera with regard to Daraprim.

Do the specialty distribution systems at Vyera benefit patients who are prescribed Daraprim?

A. They do. You want me to expand on that?

Q. Yes, please.

A. They do because of the high price of the product. After Vyera increased the price, retail pharmacies would no longer carry it. Even if Vyera had allowed them to, they wouldn't stock a product that is that expensive.

It's also a small patient population. So a retail store to have a product that pricey on its shelf, waiting for a potential patient to come in, doesn't make good business sense to them, as well as it is an orphan disease or an orphan condition. And many of those products, because they are higher price, tend to be distributed through a specialty pharmacy network.

Q. Does the specialty pharmacy network have benefits to patients?

A. Sorry. Yes. The specialty pharmacy a lot of times will do the intake on the patient. So they look at the benefits, the insurance benefits. They contact the insurance company, work with them if they need a prior authorization or other medical information from the doctor. They coordinate with the doctor. They coordinate with the patient. They apply any copay benefits or if there is a Medicare -- I forgot what we called it. It's a Medicare charitable network that will contribute to the price of the product. They will apply that, potentially. If it's an indigent patient or uninsured patient, they will potentially give them benefits as well, and then they will contact the patient, ship to the patient so they kind of become the one-stop shop for the patient and the doctor and the insurance.

Q. Thank you.

Earlier I think you used the word in reference to these programs, patient assistance programs. Did I have that correct?

A. Yes.

Q. What are patient assistance programs?

A. There is a variety of then. The most common is copay cards, copay benefits. If an insurance company will cover the product for the patient but the patient has to pay $150 out of pocket or some price, a lot of times the copay programs will step in and support bringing that out of pocket to the patient,

bringing it down, making it more affordable to the patient, and the manufacturer, the pharmaceutical company, pays for that, so they pay for those benefits to the patient.

They also -- like I said, they do these -- they used to, I don't know if it's allowed anymore, but there were these Medicare charitable organizations that you can contribute to that would, if you had a Medicare patient that had an out-of-pocket price that was unaffordable, they would step in and help to bring that cost to the patient down so that patient could access the medicine.

Also, programs for indigent patients, if they made a certain income per year, you do that based on the federal poverty limit.

And then there are also patients, like cash programs for patients who are uninsured. And the pharmaceutical company will typically, for patients who are truly uninsured, will sell that product to the patient for a much reduced price so the patient can have access to the medicine.

Q. When Daraprim is distributed through specialty pharmacies as you have described, does this system increase the adherence of the patient to the medication regimen?

A. It's technically supposed to. Sometimes it doesn't because of the mail order component of it. Just receiving the call from the specialty pharmacy, somebody has to be at home to get it. It slows down the process a bit. But it is typically

looked at as helping the patient adhere to the medication in the way that it is supposed to be taken.

Q. Thank you.

Now, did Vyera fund a foundation to help patients if there were affordability issues with affording Daraprim?

A. Yes. There are multiple -- Vyera had multiple patient affordability programs.

Q. Can you explain for the Court what those were.

A. So there was -- I believe there was a copay card that would help commercial patients, patients who had a commercial insurance. There was a Medicare foundation, charitable foundation that would disseminate funds according to whether or not that patient qualified. And if they needed help and couldn't access the medicine because the out-of-pocket was too high, there was indigent patient support. And when we created that, we actually did a much higher limit for federal poverty limit. So we expanded the number that group of patients who would qualify for that program.

I don't think that there was a cash program. There was also, I think -- early on, there was the move to decrease the price, the price to hospitals, institutions. I believe we cut the price by half per institutions to make the product more affordable for them to stock. And I believe we also came out with a 30-count bottle, again, because it's a very small patient population. So to have a 100-count bottle sitting on

the shelf taking up cash and eating into your inventory didn't make sense. So maybe giving them a smaller-count bottle would make it more affordable, and they would be able to stock in case a patient came in.

Q. You mentioned earlier today the 340B program. Can you explain what that is.

A. Yeah. The 340B, and I wasn't aware of this program before I worked for Vyera, the 340B program is a program, it's a national program that covers -- it covers certain institutions. The institutions have to have, I believe -- over 50 or 60 percent of the patients within their system have to be within a certain level of the poverty limit. Essentially, it's a program for institutions to buy product at a cheaper price to distribute to those patients. The price that they get it at for Daraprim, when we bought it, was a penny a pill, so they were able to buy a 100-count bottle for a dollar.

Q. Do you know as a percentage basis how many of the patients who are on Daraprim received Daraprim for a penny a pill?

A. The only thing I know, I didn't know the patient part of it because there is not really a way to see that once it goes into an institution. But what I could track was, I think it was 50 to 60 percent of sales were going into a channel, a sales channel that was for a penny a pill. So it was at that greatly reduced price.

Q. Just to get back to the 340B issue as it came up earlier

about the diversion issue, could you explain that in more detail, so I understand it, exactly what the concern was there.
A. Sure. I'm not an expert on this. It's a fairly complicated system. But my understanding when we started talking to institutions and trying to understand the process of the 340B system is that when hospitals buy product at that 340B price, that greatly reduced price, they are supposed to, when they have it in the pharmacy, they are supposed to hold it separately from product that is meant for commercial patients.

When a patient comes in, they are typically supposed to determine if that patient has commercial insurance and, potentially, the commercial insurance will pay for the product, or part of the product, or if it's a patient who qualifies for that 340B benefit, and they get the product at the very, very low price.

What we have heard, and I think it's been kind of a common discussion in the pharmaceutical industry, is that hospitals will sometimes mix the product, and they will buy 340B product at a greatly reduced price and then use it for commercial patients and get the payment from the commercial insurance.

Again, I'm not an expert on this, so I may have some of my facts wrong. But when we had these discussions, those were the points that were made, and I believe we talked to consultants, and we also talked to people internally who knew a

lot more about it than I did.

Q. That's helpful.

The concern -- I believe you testified that that was one of the motivating reasons for the bottle limits that you testified about, is that right?

A. Correct.

Q. Can you explain that part of it. What is the connection between those two things?

A. Say if we are looking at the State of Georgia. The institutions there had -- typically, if I summed them all up, the institutions there had been buying 50 bottles a year, and we had historical data.

If they had been buying 50 bottles historically a year of Daraprim, and even at the lower price, that kind of indicates to me that that's the demand in that market. You get some spurts sometimes, you get some outbreaks, but, again, it's a really, really small patient population. Then we buy it, we increase the price. And, all of a sudden, we are seeing institutions buying at one fell swoop 40 bottles, 50 bottles. That's a clear deviation from what was happening before.

So the thought was, from the BD team, potentially it's going to a generic, I don't know how that would happen mechanistically, or maybe they are buying it at that low price, and they are using it to give to commercial patients and they are pocketing the difference, ultimately cannibalizing the

sales that we may have had from those commercial patients in a more normal scenario.

Q. Just so I'm clear, this is something the business development team told you that they were concerned about?

A. No. Their primary concern, I believe, was the issue around the generic accessibility. I think we had a patient-access person that was working with us, and I think from that person we started thinking about this 340B diversion issue. Again, it's something that's been in the news. You can Google it. It is clear that it wasn't just Vyera that was having those concerns. There were sort of persistent concerns in the pharmaceutical industry.

Q. Thank you for that.

I want to go back to an e-mail that you were shown earlier. It's GX-1302.

MR. CASEY: Justin, if you could get that, please.

Q. Do you have it up there on the screen, Ms. Ghorban?

A. Yes.

Q. Do you remember being asked questions about this document?

A. Yes.

Q. I'd like to direct your attention to the bottom of page 1302-001, that e-mail. You were asked about this phrase: The priority work stream is to ensure the product is moved into close distribution as swiftly as possible in order to minimize exposure. Do you see that?

A. Yes.
Q. You were asked about that. Do you remember that?
A. Yes.
Q. I believe your testimony was that you believe that minimized exposure meant minimized exposure to generic competitors getting access to Daraprim?
A. Yes.
Q. Is that your testimony?
A. Yes.
Q. Do you recall, Ms. Ghorban, having your deposition taken in this case on January 6 of 2021?
A. Yeah.
MR. CASEY: Can I have the deposition transcript, please, at page 70, line 12.
Q. Ms. Ghorban, everything you said in your deposition was true and accurate, correct?
A. Yes.
Q. At page 70, starting at line 12, do you see it there you were asked:
Do you understand what Ms. Retzlaff meant when she said that the priority work stream was to move it into closed distribution as swiftly as possible in order to minimize exposure. Do you know what she meant by minimize exposure?
Your answer was: I -- I think when I read it, I don't -- I don't remember exactly what she meant when she said

minimize exposure. I'm assuming it's around generic accessibility or accessibility of the product to generics.

Do you see that?

A. Yes.

Q. At the time of your deposition you were assuming that. You didn't actually know that for a fact, correct?

A. Yeah. I think the wording exposure, to me, it is like risk. That's the reason why I would say it's equivalent to risk, having an open distribution system in the context of the discussions we had.

Q. Do you actually know what Ms. Retzlaff meant by that phrase, minimized exposure?

A. I can't speak for her.

Q. So the answer is no?

A. No.

Q. Ms. Ghorban, you were asked at the beginning of examination about your long experience in the pharmaceutical industry, 20 years of experience. Based upon that experience, do you believe it's possible to keep generic companies from accessing drug products?

A. I think it would be very hard to keep them from accessing it. But I don't know -- again, I haven't worked in the generics business, so I don't know how they acquire product to do their testing to show that it's equivalent.

Q. Again, if I could go back to that deposition again. I am

going to direct you to page 74 of your deposition, starting at line 22.

You said: I mean, I think the one comment I would make is preventing generic entry was something that I don't think was possible. I still don't believe it's possible.

You see that?

A. Yes.

MX. BLACK: Your Honor, I object to foundation.

THE COURT: Sustained. Stricken.

Q. You talked a little bit earlier about the expansion of the distribution system. I would like to direct your attention to that testimony.

The specialty distribution system that Vyera used to distribute Daraprim was inherited from the prior owner of Daraprim, a company called Impax, correct?

A. Yes.

Q. Specifically, Vyera inherited a contract that Impax had with ICS as a 3PL selling to hospitals, correct?

A. Correct.

Q. What is a 3PL?

A. As I know it, a 3PL -- and, again, this was not my area of expertise when I was at Vyera or before or since. But the 3PL, as I understand it, is a company that works with a pharmaceutical manufacturer. Part of what they do is hold inventory, and then they are equipped to sell inventory to

wholesalers, to specialty pharmacies, to institutions, etc. They are kind of your key partner in terms of knowing where the product goes and keeping the product that you have, the finished inventory saved.

Q. Vyera also inherited a contract that Impax had with Walgreens specialty pharmacy, correct?

A. Correct.

Q. You were asked about issues of access following the acquisition of Daraprim. Can you explain what the reasons were for the access issues after the acquisition of Daraprim?

MX. BLACK: Your Honor. I object. Beyond the scope of my direct examination.

MR. CASEY: I'll withdraw it, your Honor.

Q. Ms. Ghorban, after the acquisition of Daraprim, did Vyera realize that the distribution agreements it had inherited from Impax were not adequate to meet the needs of Vyera's prescribers and patients?

A. Yes.

Q. What, if anything, did Vyera do about that?

A. We started trying to understand what the needs were for physicians. We didn't understand that the turnaround time to getting product to patient was more urgent than a specialty pharmacist could sometimes manage.

We started to look at ICS and how they were able to sell to institutions. It turned out they were not very well

equipped to sell to institutions because there was an account set up that most institutions didn't have, so we added ASD to distribute to institutions.

We added Cardinal because a lot of institutions, I believe, had agreements already with Cardinal and had to buy exclusively from Cardinal.

We added the hub to ensure that patients were able to access the benefits, the copay benefits and the affordability benefits that we were offering, and expanded the specialty pharmacy network to ensure that no matter where the patient was in terms of geography and also who the patient's commercial insurance was, because commercial insurance is also partner with specialty pharmacies, no matter where they were and what they needed, they were able to get it. It wasn't a hundred percent, but we tried to meet the needs of the patients and the prescribers.

Q. You mentioned a hub program. What is that?

A. A hub program is -- it functions like a specialty pharmacy except for it is sort of the hub of the specialty pharmacy wheel. If you think about the specialty pharmacies as the spokes, the hub is the key intake for the patient and then we will do all the work on the affordability, the insurance, and then we will send that prescription, once it's ready to be dispensed, it will send that to a specialty pharmacy. The specialty pharmacy will reach out to the patient and will send

the product to the patient.

Q. Once the hub model was instituted, was Walgreens replaced as the exclusive specialty distributor of Daraprim?

A. They weren't replaced. They were no longer the exclusive pharmacy, specialty pharmacy. It was an add-on.

Q. And you added specialty pharmacy in addition to Walgreens, correct?

A. Yes.

Q. You also were asked about ADAP programs. I think you said they are an AIDS Drug Assistance Program?

A. Yes.

Q. Can you explain what they are.

A. Again, it's really complicated, but I believe that it's state run and it's essentially an assistance program that was set up during the epidemic of AIDS and HIV to support patients at a local level.

So what we found was that there were ADAPs in certain states that couldn't access the product. Either they couldn't establish an account with ICS or -- again, the mechanism is very confusing to me. But, essentially, we had to do something to make sure that they could buy product, and they could buy product at the 340B price, so they were buying it at a penny a pill. But we had to expand to include them as customers to ensure that they could buy the product and disseminate it to their patient.

Q. So Vyera expanded the distribution of Daraprim to include ADAPs?
A. Yes.
Q. And all of these additional distribution outlets broadened the accessibility of Daraprim, correct?
A. That was the intent, yes.
Q. In fact, that's what happened, correct?
A. I believe so.
Q. Did you consider these changes to the distribution system of Daraprim to be improvements?
A. Yes.
Q. You testified earlier about the 30-pill Daraprim bottle for hospitals.
A. Yes.
Q. Did Vyera also create sample packs for hospitals?
A. Sample packs can't go through hospitals, but we created sample packs for prescribing physicians in the typical clinic setting.
Q. What is a sample pack?
A. A sample pack is just a small number of pills. Usually, doctors often have them in their offices, and they will give them to patients to see if patients react well to the product, if it helps, if they have a reaction. They can also be used as starters to start a patient on medication.
The way that we used it for Daraprim was sort of as a

bridge for while the patient was waiting for the product from the specialty pharmacy, that they didn't have to wait, and potentially it was readily available to them. If the doctor -- I think we had a mailing system for the samples. But it should have been more readily available than sometimes waiting for insurance to clear the approval on the product.

Q. Thank you.

You were also asked some questions about Vyera buying back bottles or the bottle limits, rather. I'm sorry.

Withdraw that question.

I'd like to discuss the IQVIA data questions you were asked.

Was the reporting of sales data to data-reporting companies a deciding factor in any of Vyera's contracts?

A. No. It was a request. It didn't decide whether or not we were work with certain partners.

Q. There are alternatives to IQVIA data, correct?

A. There are alternatives. There is also historical data that doesn't go away if you decide not to share the data going forward. There is still historical data.

Q. What are some of the alternatives?

A. Symphony is a data source. A lot of times you will look at a company -- if you are looking to acquire a product from a company, you will look at a company's financial reports, so their 10-Ks and their 10-Qs. A lot of times they will report

volume of sales there. That's typically one of the steps -- when you do an assessment, that's one of the steps you take.

There are other sort of reporting companies that aggregate information on certain therapeutic areas, certain products, certain companies that sometimes you can find that data in. It depends on how public it is.

Q. Thank you.

The reliability of IQVIA data depends on the drug, correct?

A. Correct.

Q. Can you explain that?

A. For products that treat -- that aren't as large, so for a very large product, like a Lipitor, the data would be pretty solid because there is a lot of volume there. For products that treat orphan indications, small patient populations disseminated through hospitals or disseminated through clinics, say the doctor buys it and distributes it directly to patients, the data is not as robust for those different types of medications.

Q. So you have already testified that Daraprim was a small patient population, correct?

A. Correct.

Q. If I understand you, the IQVIA data would not be as reliable for Daraprim data, correct?

A. Correct. It might not capture just because it's not as

large -- it's not as large of a product.
Q. Because of these limitations on the data, it's not a decision-making tool, correct?
A. For certain products it's not a decision-making tool. You'd have to go further to look at other data sources if you are looking at a product to acquire. For other products, where it is reliable, you would use that data source pretty heavily.
Q. But in terms of Daraprim, which is, as you have testified, a small patient population where the data is not as reliable, it would not be a decision making tool for assessing the Daraprim market, right?
A. I think we would -- we looked at the data, but -- and it factors into the conversation and the analysis, but it wouldn't be a single factor that would make a decision for us.
Q. No one would decide to acquire a product based solely on IQVIA data, correct?
A. No. That's not the process of acquisition.
Q. No meaning --
A. No. You would never use just a data source to make a decision on whether or not to buy a product.
Q. Thank you, Ms. Ghorban. I have no further questions.
THE COURT: Any redirect?
MX. BLACK: Yes, your Honor.
REDIRECT EXAMINATION
BY MX. BLACK:

Q. Ms. Ghorban, you testified a moment ago about specialty benefits of high-cost drugs. Do you recall that?
A. I'm sorry. Specialty benefits?
Q. Yeah. To high-cost drugs.
A. Benefits of being distributed in specialty pharmacies?
Q. Yes.
A. Yes.
Q. Martin Shkreli made Daraprim a high-cost drug, correct?
A. Yes.
Q. It was not a high-cost drug for 60 years?
A. When we -- when Vyera acquired it, it was not what I considered to be a high-cost drug.
Q. And you said that high-cost drugs with small patient populations benefit from being distributed in specialty. Do you recall that?
A. Yes.
Q. Because it makes it harder to stock for pharmacies?
A. It makes -- when you have a high-cost product for a low-patient population, it's hard -- it's unaffordable for retail pharmacies to stock it, and also you have issues with insurance. So specialty pharmacies or hub models help on both those points in terms of stocking, as well as working with insurance.
Q. Daraprim has always been a small patient population drug, correct?

A. Yes.
Q. Before the price increase that Martin Shkreli implemented, the small patient population did not present stocking issues, correct?
A. Not that I'm aware of.
Q. Ms. Ghorban, you also testified in response to Mr. Casey's question that specialty distribution technically is supposed to improve patient compliance. Do you recall that?
A. Yes.
Q. Do you know if patient compliance actually increased after the transition to specialty distribution for Daraprim?
A. I don't have a comparator for before Vyera acquired it to say that it improved or decreased patient compliance.
Q. So patient compliance might have actually decreased after the transition to specialty?
A. I don't know. I don't have a comparator.
Q. And you testified a moment ago about 340B programs. Do you recall that?
A. Yes.
Q. 340B program, it's a federal program, correct?
A. I believe so.
Q. It's not a program that Vyera created?
A. No.
Q. You also testified a minute ago about using historical IQVIA data for Daraprim. Do you remember that?

A. Yes.
Q. Would historical IQVIA data be reliable after Vyera's price increase?
A. Because it's a small patient population, I don't know that it would have been accurate. I've seen products that are high priced more recently that the sales are inaccurate in IQVIA, and I can't say whether or not it would have been accurate.
Q. Daraprim volume declined after the price increase, correct?
A. I believe it did.
Q. It significantly declined, correct?
A. I believe so.
Q. And given the decline in volume, historical IQVIA data after the price increase would not be representative of Daraprim volume sales -- let me start it over.

Given the decline in volume in historical IQVIA data before the price increase would not have been representative of Daraprim volume sales after the price increase, correct?

MR. CASEY: Objection, your Honor. She is going beyond the scope of the cross-examination. I don't know where this is going.

THE COURT: Excuse me one second.

Overruled.

(Continued on next page)

A. I'm sorry, can you repeat that question?
Q. Yes.
Given the decline in Daraprim volume after the price increase, the historical IQVIA data, before the price increase, would not have been representative of Daraprim volume sales after the price increase, correct?
A. I believe so, because the sales -- there's a couple of sources of sales, but, yeah, the price is factored into the sales as IQVIA reports it.
Q. In other words, generic companies could not have just looked at historical IQVIA data after the price increase to figure out the Daraprim market opportunity, correct?
A. They could -- usually, you look at it in two ways. You look at the volume of the prescriptions, and you look at the sales. And so they could potentially -- assuming the sales were captured appropriately, given it's a small patient population, they could look historically and see that the volume was, you know, for example, 10,000 prescriptions a year. They could see that. And they knew the new price, so they could do the calculation, but the sales would be different because IQVIA considers the sale price when it reports volume -- I'm sorry, when it reports the sales.
Q. You mentioned that Daraprim was a small patient population drug before, correct?
A. Yes.

Q. And, yet, you used IQVIA data as a starting point in your analysis for Daraprim acquisition, correct?
A. Yes.
Q. You also talked earlier about expanding the Daraprim distribution system that Vyera inherited from previous owners.
Do you remember that?
A. Yes.
Q. But given the system that you've described with additional customers, it had customer restrictions on authorized classes of trade, correct, that Vyera could sell Daraprim to?
A. Yes, it did.
Q. You also added purchase limits, correct?
A. Correct.
Q. That previous owners did not have?
A. I don't believe they had them, no.
Q. Let me stop there.
MX. BLACK: That's all I have.
THE COURT: Any additional cross?
MR. CASEY: No, your Honor.
THE COURT: Thank you.
So what caused you to leave Vyera?
THE WITNESS: It was a very distressing place to work. It was stressful, it was not fulfilling, and it was just not a good environment to be in.
THE COURT: Does any counsel have any question for

this witness based on the question I just asked her?

MX. BLACK: No, your Honor.

MR. CASEY: No, your Honor.

THE COURT: You may step down.

(Witness excused)

THE COURT: Next witness.

MR. MEIER: Yes, your Honor. The government, at this time, calls Frank Della Fera, and my colleague, Neal Perlman, will be handling this witness. This witness is with a declaration.

THE COURT: So, Mr. Della Fera, if you could come up here, please, and take the witness stand and remain standing.

FRANK DELLA FERA,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

THE COURT: You may take off your mask.

You're being handed a document, counsel. What is the exhibit number?

MR. PERLMAN: 8007, your Honor.

THE COURT: Thank you.

And, Mr. Della Fera, if you would look at page 17, is that your signature on this document?

Oh, Mr. Della Fera, I forgot to do something important. Could you please state your name for the record.

THE WITNESS: Frank Della Fera.

THE COURT: And could you spell your last name, please?

THE WITNESS: D-e-l-l-a F-e-r-a.

THE COURT: And is that two words?

THE WITNESS: Yes.

THE COURT: So it's capital D and capital F?

THE WITNESS: Correct.

THE COURT: Thank you.

And if you could look now at Government Exhibit 8007, which I believe is at the front of your binder. And page 17, is that your signature on that document?

THE WITNESS: Yes.

THE COURT: Before signing that document, did you read it with care?

THE WITNESS: Yes.

THE COURT: Do you swear to the truth of its contents?

THE WITNESS: Yes.

THE COURT: Any objections to the receipt of Government Exhibit 8007?

MR. POLLACK: Yes. Good afternoon, your Honor. Jeff Pollack, on behalf of the defendant.

Your Honor, first off, and I think the colloquy we just did may have addressed this already, but I did want to raise that your Honor's procedures require the submissions of affidavits as sworn testimony, and Mr. Della Fera's statement

is not sworn or --

THE COURT: You have to keep your mask on until you're at the podium. Thank you so much.

MR. POLLACK: May I move to the podium where I don't have to have my mask on?

THE COURT: You may.

MR. POLLACK: Thank you, your Honor.

So, your Honor, I was saying that perhaps the colloquy we just went through addresses this, but your Honor's procedures do require affidavits, and the written statement that Mr. Della Fera submitted was not sworn. I only raise it as a point of procedure, and your Honor will guide us appropriately on that.

THE COURT: Oh. Thank you.

Yes, of course, the testimony given in court must be sworn, but I think the witness has just done that, and that's sufficient.

MR. POLLACK: Okay. Very good.

Your Honor, we do have some objections. Allow me to grab -- paragraph 40 of Mr. Della Fera's affidavit, he recites a conversation that he had with an individual, Mr. Valiveti, about something that he was informed about from former Vyera employee Kevin Mulleady. Your Honor, we object to this paragraph as hearsay.

THE COURT: Give me just one second, please.

I'm on page 12, paragraph 40?

MR. POLLACK: Correct.

THE COURT: I think that's -- well, I'll hear from plaintiffs' counsel, but I think that's just received not for the truth, but for the fact that it was said by Mr. Valiveti to the witness.

Am I right?

MR. PERLMAN: Correct, your Honor.

THE COURT: It's received in that vein.

(Government's Exhibit 8007 received in evidence)

MR. POLLACK: Your Honor, then I turn us next to paragraph 46, and specifically, I look down to beginning with, I believe it's, the third to last sentence, three lines from the bottom, where it begins "it is my view," where Mr. Della Fera says, "It's my view that if we had used Fukuzyu as our pyrimethamine API supplier, Vyera would have been able to respond within the review period," referring to the review period for their ANDA submission. Your Honor, I submit that is speculation and improper lay opinion.

Mr. Della Fera has, admittedly, a lengthy career in the pharmaceutical industry, but except for one year in which he was the president of Sandoz, he spent the remainder in sales and marketing, and it does not appear that there's a foundation laid for that statement in his affidavit.

THE COURT: Overruled. Obviously, he is testifying

here as someone knowledgeable about his company's business and judgments made during the course of that business. I'll receive it as proper lay opinion under 701.

MR. POLLACK: And, your Honor, before we proceed, I believe that plaintiffs' counsel was going to move in some evidence. I'd like to know what's in evidence on the affidavit before we begin.

THE COURT: I'm happy to rule on any other objections that you have. This objection is overruled.

I'm sorry, what do you mean? Which exhibits?

MR. POLLACK: There was one document referenced in the affidavit that we do have an evidentiary objection to. There was two that we've resolved with counsel. The one that's an objection is GX 3286.

Justin, if we could pull that up?

This is a summary document --

If we go to page 2, Justin.

-- a summary document of a series of events recorded by Mr. Della Fera's employee, Scott, I believe his last name is --

THE COURT: Florentino.

MR. POLLACK: Florentino, yes. Thank you very much.

-- Scott Florentino at the top.

And, your Honor, this is a hearsay document. It cannot fall under the business records exception. The record

must be made at or near the time of the events discussed. This was made in 2018, and the events go all the way back to '16. When we talk about events involving Vyera, the earliest Vyera meeting is in April of 2018 on this document.

Additionally, your Honor, it has to be created by someone with knowledge. When we look at this document --

And, Justin, if we could find the entry for May 14 of 2018.

-- we see here that there was a meeting with attendees Kevin, meaning Mr. Mulleady, and Frank, meaning Mr. Della Fera. Mr. Florentino was not even present here. And if we look below May 8, 2018, it does not even reference who the attendees were in this meeting.

So in addition to not being a business record, this document has several layers of hearsay within hearsay and sometimes within hearsay, and, therefore, would be an inadmissible record.

THE COURT: Where is this referenced in the affidavit? What paragraph? So I can see the purpose for which it's being offered.

MR. POLLACK: Your Honor, this is referenced in paragraph 51 of the affidavit.

THE COURT: Thank you.

Let me ask plaintiffs' counsel if you want to address the objection. Are you offering 3286?

MR. PERLMAN: Yes, your Honor, we are. And we actually, also, have one of the 9000 series documents with a large bulk of the remaining exhibits in Mr. Della Fera's affidavit, as well, to enter.

For GX 3286, we believe this is a contemporary business record compiled by a Fera employee to memorialize a series of meetings between Fera and Vyera. As it says in paragraph 51, Mr. Della Fera directed Mr. Florentino to memorialize these events as listed. And I can lay, on redirect, additional foundation to support the fact that it's Fera's practice to memorial discussions with outside parties such as this one.

THE COURT: So I'll receive it subject to connection, and I will ask defense counsel if they feel, on redirect, a sufficient basis hasn't been laid, or if the cross-examination also suggests that I should not receive this, I will allow a renewed objection.

Is that agreeable, counsel?

MR. POLLACK: Thank you, your Honor.

THE COURT: Good.

Anything else?

MR. POLLACK: Nother further. And we're ready to proceed.

THE COURT: Thank you so much.

Hold on one second, because I think there was going to

be an additional offer of evidence, and then we'll begin cross-examination.

MR. POLLACK: Your Honor, one point I would make is that Mr. Della Fera is not the only employee of Fera who's present today. His coworker, Susan McDougal, is also present, and I would ask to sequester the witness.

THE COURT: Yes, unless the parties agree otherwise, all witnesses are sequestered until their testimony is done except for expert witnesses. That's the general rule.

MR. POLLACK: Thank you, your Honor.

MR. PERLMAN: No objection, your Honor.

Your Honor, may I approach?

This is GX 9008. It has 10 of the documents from Mr. Della Fera and Ms. McDougal's affidavits. There are three remaining, for which we did not resolve the dispute until 1:45 today, so they're not on this list.

THE COURT: Any objection to the receipt of GX 9008 and the documents listed therein?

MR. POLLACK: None subject to your Honor's previous rulings. Thank you.

THE COURT: Received.

(Government's Exhibit 9008 received in evidence)

THE COURT: Cross-examination.

MR. POLLACK: Thank you, your Honor.

CROSS-EXAMINATION

BY MR. POLLACK:

Q. Good afternoon, Mr. Della Fera. How are you?

A. Good, thank you.

Q. I don't know if you heard, but my name is Jeff Pollack. I'm an attorney for Duane Morris, representing the defendant, Martin Shkreli, in this case. Thank you for being here and answering my questions today.

Mr. Della Fera, your written statement was just admitted into evidence. There were other drafts of that statement, correct?

A. Of the affidavit?

Q. Yes.

A. Yes.

MR. POLLACK: Justin, can we bring up DX 556, please.

Your Honor, may I approach?

THE COURT: You don't need to ask permission, counsel.

MR. POLLACK: Thank you, your Honor.

THE COURT: Thank you.

MR. POLLACK: Your Honor, what's the procedure? Do I hand it directly to the witness or to your staff?

THE COURT: You may hand it directly to the witness.

MR. POLLACK: Thank you.

BY MR. POLLACK:

Q. Mr. Della Fera.

A. Thank you.

Q. Sure.

Mr. Della Fera, I've just handed to you what we've marked as Exhibit DX 556. This is a copy of the first draft of your written testimony provided to us by the FTC's attorneys on Friday afternoon.

THE COURT: I'm sorry, you can't testify, counsel.

MR. POLLACK: Okay.

Q. Mr. Della Fera, have you seen this document before?

A. I have to read the whole thing if you're asking me, but, yes, it looks familiar to the affidavit, yes.

Q. Does that appear to be your first draft of your affidavit?

A. If you say so.

Q. Is it your name on the last page of that document?

A. No.

Q. Which document -- what name is on the document?

A. Witness name.

Q. It just says "witness name"?

A. Uh-huh.

Q. Okay.

Turn to the front.

You're absolutely right. My mistake.

That's your name on the front of the document, correct?

A. Yes.

Q. Can you tell us, just explain, the process by which you received a draft affidavit from the FTC?

I'm sorry, let me rephrase because I'm assuming facts.

Who sent you your first draft of your affidavit; do you know?

A. My counsel.

Q. Do you know who he got it from?

A. My counsel worked probably with the FTC, I believe.

Q. When did you receive the first draft?

A. I don't remember the date.

Q. How long before -- well, first of all, your affidavit itself is dated October 18, 2021.

How long before that did you receive the first draft of your affidavit?

A. I really don't recall, but a month or two.

Q. When you received it, did you review it?

A. Yes.

Q. Did you make any changes?

A. Yes.

Q. How many changes did you make; do you recall?

A. No.

Q. From my review, it appears to be essentially the same document. Would you agree with that?

A. I have not reviewed the two documents, but I do know which one I signed.

Q. And you don't recall how many changes you made?
A. No.
Q. And you don't recall if you signed, essentially, the same document that your lawyer sent to you on day one?
A. I don't know where you're going with that, counsel. I signed a document that was received from the counsel from FTC just minutes ago — that's what I have in my hand — and then you sent me a copy here. I have not reviewed the copy. I'm just listening to your questions.
Q. Mr. Della Fera, did you make any substantive changes to the initial draft you received?
A. I don't recall.
Q. Let's talk about Fera Pharmaceuticals and its business.

Fera offers and sells generic and branded pharmaceuticals, correct?
A. Yes.
Q. Your generic business model, as I understand it, is to identify and develop products that have barriers to entry that would otherwise deter your competitors; is that right?
A. The word "deter" or less likely.
Q. And Fera isn't interested, then, in investing in making a generic drug for which there's already a lot of competition, is it?
A. No, we normally would not have an interest for that.
Q. Is it correct -- I think you said before that in

determining which pharmaceuticals to pursue, Fera wants to ensure that it, meaning the branded pharmaceutical product -- strike that.

Some of the barriers that Fera looks at, Mr. Della Fera, are whether the drug was a complex formulation, the type of its dosage form, and the unavailability of API? Are those some of the barriers that you look for?

A. Yes.

Q. And as to API, as I understand it, figure out if that is limited, your employees need to call around to every possible manufacturer, correct?

A. Yes, hopefully.

Q. And what does it mean for API to be limited?

A. Limited is usually one supplier to -- one supplier in the market.

Q. Why does your company, Fera, see that as a benefit to pursuing a generic pharmaceutical?

A. Less competition, potentially, going forward, but there is no guarantee.

Q. How does having limited API lead to less competition for Fera Pharmaceuticals?

A. Our hallmark is to have niche-type products, products that are limited in availability, and to help the market have access to a lower cost product.

Q. So for your company, limited API is not a deterrent to

entry, but it's something that you see as a benefit?
A. In some cases, yes.
Q. Did you see it as a benefit when evaluating Daraprim?
A. Yes.
Q. Now, there are also data sources available that identify which companies manufacture and offer for sale API, correct?
A. Yes.
Q. One of those data sources is the Newport database; am I right?
A. Correct.
Q. Fera uses that Newport database to identify API manufacturers; is that right?
A. Yes.
Q. Now, specifically to Daraprim, in September of 2015, your company, Fera Pharmaceuticals, decided to develop a generic Daraprim after seeing press coverage about Vyera's price increase, right?
A. When we decided to pursue the product, yes.
Q. And the first thing you did to assess market opportunity was that your company accessed, I believe — correct me if I'm not pronouncing it right — IQVIA data from 2014?
A. Yes.
Q. And from that data, your company was able to ascertain that the annual sales of Daraprim was approximately 1 million tablets, correct?

A. That is correct.
Q. And from that, was Fera able to forecast the market opportunity for generic Daraprim?
A. Yes.
Q. When you looked at that IQVIA data, your company was aware that prescribers were also using other drugs, such as Bactrim, instead of Daraprim because of Bactrim's lower price, correct?
A. At that time, no, we were not looking at Bactrim data. Bactrim is a very broad spectrum antibiotic. I think there's like 800 million tablets in the U.S. market. So I would not be looking at that, no.
Q. Were you aware at some point that Bactrim was being used as a substitute for Daraprim?
A. Yes, when it hit the media, where healthcare professionals, especially in hospitals, institutions, who were concerned with the extraordinary costs of Daraprim, they were mentioning to use Daraprim as a second line instead of a first line, and to utilize Bactrim or Bactrim alternatives similar to generics as the first line.
Q. When you say "hit the press," when what hit the press?
A. I'm trying to recall — late 2015 or '16, I don't remember the dates or times — but in that general time there was a lot of media attention drawn to the company Vyera.
Q. Another thing that your company was aware of was that prescribers were switching to compounded pyrimethamine as a

substitute for Daraprim, correct?
A. I heard about that, but I wasn't -- I'm not familiar with the compound, so -- it's still in those articles, they were definitely out there.
Q. And, in fact, after your company had manufactured its own source of API, a compounder actually reached out to your company to purchase API, correct?
A. Yes.
Q. And by API, I mean pyrimethamine API; are we on the same page?
A. Correct. And we did not sell to the compounder.
Q. But someone contacted you for it, correct?
A. Yes.
Q. Do you recall which compounder that was?
A. No.
Q. You shook your head, and I think you said no. Which one was it?
A. It's no.
Q. Okay. Thank you.
A. But if you want to refresh my memory, if there are any documents I don't remember looking at...
Q. Now, Mr. Della Fera, after your company looked at the IQVIA data in 2015, did you estimate that sales would drop 50 percent in the first year?
A. You know, as time goes on — it's six years — we made a lot

of different estimates, and it's mostly on discussions. That would have been a good guess, Jeff, but I don't recall putting that in writing or anything else, but it sounds like a good guess.

Q. Was that a yes?

A. Yes.

Q. And later, in 2018 --

THE COURT: I'm sorry, a 50 percent drop of what?

MR. POLLACK: You're absolutely right.

THE COURT: Counsel, I don't know what that question and answer referred to.

MR. POLLACK: You're absolutely right. Let me correct the record.

Mr. Della Fera, when we're talking 50 percent your firm projected a 50 percent drop in sales of Daraprim in the first year after the price increase, correct?

THE WITNESS: And I think Jeff means the unit tablets, from a million tablets down to 500,000 tablets.

Q. And even with the projection of 1 million tablets to 500,000 tablets, you and your company still viewed generic Daraprim as an attractive opportunity to develop a product, correct?

A. Yes.

Q. And I started off talking about -- fast-forward three years down the road, in 2018, you have a meeting with Vyera's then

CEO, Mr. Mulleady, correct?
A. Yes.
Q. And from Mr. Mulleady, am I right that you learned that the sales of Daraprim had actually decreased down to approximately 300,000, correct?
A. That is correct.
Q. It was about a 70 percent drop?
A. Correct. From Mr. Mulleady's share, the data from the company that was accurate.
Q. Did you believe the data to be accurate?
A. I didn't see any reason for him not to be telling the truth, but I still don't know if it's accurate.
Q. Did your company perform projections based on that data?
A. Yes.
Q. And after you did your projections, did you still view generic Daraprim as an attractive opportunity for your company?
A. Yes.
Q. Let's switch topics for a moment and talk about API sourcing.

Mr. Della Fera, we'll be very careful not to use the name of your API supplier. We're going to refer to it as API Company 1.

A. Thank you.
Q. If I say that, you'll understand who I'm referring to, correct?

A. Correct.
Q. Before I get there, would you agree with me that pyrimethamine is not a difficult molecule to manufacture?
A. Agreed.
Q. When you started out looking at Daraprim and you looked at the Newport database -- first of all, was it you who looked at the database, or someone else at your company?
A. It was not me.
Q. Who did that work? Do you know?
A. I would say Susan McDougal.
Q. Okay, your colleague, Ms. McDougal?
A. Yes.
Q. She's your vice president?
A. Yes.
Q. Is she vice president of something specific or vice president of the company overall?
A. She's recently been promoted to executive vice president of the company.
Q. In 2018, what was her title? Sorry, 2015; correct myself.
A. I don't remember the title, but her responsibilities increased over that time. She was a vice president then, at that time.
Q. Well, I digress. She'll be here to testify, and we can ask her personally.
A. Thank you.

Q. With the Newport database, Fera identified two potential API suppliers with the DMF, Fukuzyu and Ipca, correct?
A. Correct.
Q. And I say Fukuzyu. I don't know if that's correct; I've heard it's not. That's what I'm used to, so if I use the word "Fukuzyu," will you understand what I mean?
A. Yes, Jeff.
Q. Okay, thank you. And feel free to do the same or however you refer to it.

According to paragraph 19 of your written testimony, your company reached out only to Fukuzyu, not to Ipca, correct?
A. I want to share that I had diabetic retinopathy, I have eyesight problems, so please bear with me.
Q. Well, Mr. Della Fera, maybe you can answer without looking at your direct testimony.

Is it correct your company reached only to Fukuzyu and not to Ipca?
A. I would believe we reached out Ipca in addition to -- I don't have it memorialized but I believe we...
Q. Paragraph 19 of your written statement says, "We reached out to Fukuzyu which was DMF pyrimethamine API, but they did not respond to our initial query," correct?

THE COURT: I'm sorry, counsel, when you read, can you read slowly --

MR. POLLACK: Yes, of course.

THE COURT: -- so we can catch every word.

So I think the statement you read was, "We first reached out to Fukuzyu, which holds a DMF for pyrimethamine API, but they did not respond to our initial inquiry."

Is that statement correct?

THE WITNESS: Yes.

BY MR. POLLACK:

Q. Your next paragraph of your affidavit says, "I then decided to meet with two potential API suppliers at an industry conference called Drug, Chemical & Associated Technologies week, usually referred to as DCAT," correct?

A. Correct.

Q. If we look in the next sentence, we see that the companies you reached out to were a company called API 1 and another company called ChemCon, correct?

A. Correct.

Q. Nothing in your affidavit here about Ipca, correct?

A. Correct.

Q. When you went to the DCAT meeting and you met with ChemCon and you met with API Company No. 1, you opted to go with API Company No. 1, correct?

A. I'm sorry, can you repeat that, Jeff?

Q. Sure. When you were at DCAT and you met with those two companies, ChemCon and API No. 1, you opted to go with API No. 1, correct?

A. Yes.
Q. And that's because API No. 1 was the more affordable option between the two, correct?
A. Affordable, and we had confidence in them executing.
Q. And API No. 1 did not have a DMF on file, correct?
A. Correct.
Q. And DMF, when we say that, we're referring to drug master file, correct?
A. Yes.
Q. That's a filing made with the FDA, correct?
A. Yes.
Q. And that's what an API manufacturer files that says that they have been approved to make a certain API?
A. Yes.
THE COURT: I'm sorry to interrupt, but does it mean that they have been approved, or if there's a DMF, they've filed?
MR. CASEY: Well, let me ask Mr. Della Fera because he's the expert.
THE WITNESS: It's not approved. They filed.
Q. They filed. Thank you.
A. And how they get approval, your Honor, is, after someone submits an application utilizing their material and then the FDA reviews the application along with reviewing the manufacturer of the active ingredient, that's when they get

approved.

Q. Thank you for that clarification.

As I understand it, your business practices, you preferred to work with a company with a DMF, correct?

A. Yes.

Q. But, in this case, you did not?

A. Yes.

THE COURT: Well, you did not work with a company with a DMF?

MR. POLLACK: That was the question.

THE COURT: Okay, but because he just said he reached out to the one company that had the DMF.

MR. POLLACK: And it did not respond.

THE COURT: Right.

BY MR. POLLACK:

Q. When you -- did you enter into a contract with API Company No. 1?

A. Yes.

Q. Do you recall when you entered into a contract with API Company No. 1?

A. It was months after the DCAT meeting, so June -- approximately June of '16.

Q. Before you contracted with API Company No. 1, did Fera conduct any kind of a tour of the facility --

A. No.

Q. -- of their facilities?
A. No.
MR. POLLACK: Justin, can we pull up DX 113, please.
Q. Mr. Della Fera, can you tell me if you have seen this document before?
A. Yes.
Q. Is this your confidentiality and exclusivity agreement entered into with company -- API Company 1 in June 13 of 2016?
A. Yes.
MR. POLLACK: Your Honor, this document is already in evidence.
But could we turn to the second page, please.
Q. If we look at paragraph 3, the document says, "Company confirms" -- "company" meaning API Company No. 1, correct?
A. I've got to read it to see the context. I'm sorry.
Q. It says, "Company confirms and agrees that during the restricted period, company will not pursue development or supply the API pyrimethamine for its account or on behalf of any other person."
A. Yes.
Q. And it says, "The term 'restricted period' means five years commencing on the effective date," correct?
A. Yes.
Q. So, in other words, this is an exclusive supply agreement between your company, Fera, and API Company No. 1?

A. That was the intention, yes.
Q. And API Company No. 1, under this agreement, cannot supply pyrimethamine API to any other company, correct?
A. Yes, because we were paying for the development personally for our company, yes.
Q. So that's a yes?
A. Yes.
Q. If we go to the next page, please, if we look at paragraph 12, we see that the term of the exclusivity period runs for the term of the agreement, five years, correct?
A. Yes.
MR. POLLACK: Can we turn to Exhibit A, please, page 115 of the document. You're on 113. Look for page FTC FERA 115.
There we go. Blow up the commercial statistics section, please.
Q. If we look here, Mr. Della Fera, it appears that API Company No. 1, if we add up the time, is predicting 34 to 40 weeks to develop pyrimethamine API, correct?
A. Approximately, yes.
Q. Ultimately, it took them longer than that to complete its first batch of API, correct?
A. Yes.
Q. But you don't know what the source of those delays were at API Company No. 1, do you?

A. No specifics, no.
Q. Whatever those delays were, was API Company No. 1 ultimately able to manufacture pyrimethamine API for Fera?
A. Yes.
Q. When was that?
A. I don't recall the timelines. There's a timeline sheet, if I could -- I don't remember.
Q. You know, Mr. Della Fera, we'll come back to that.
MR. POLLACK: Can we bring up Exhibit DX 115, please.
Q. Mr. Della Fera, what we've marked here -- can you tell me if you recognize this document, from the first page?
A. I recognize it.
Q. Is this your supply agreement between your company and API No. 1?
A. Yes.
Q. Agreed to on April 6, 2018?
A. Yes.
MR. POLLACK: Your Honor, I move to admit DX 115.
MR. PERLMAN: No objection, your Honor.
THE COURT: Received.
(Defendants' Exhibit 115 received in evidence)
BY MR. POLLACK:
Q. If we turn to page 5 of this document, Section 2.5, Mr. Della Fera, is this document, like the one we just looked at, also subject to an exclusivity agreement?

A. Can you repeat your question, please?
Q. Sure. Is this supply agreement, like your confidentiality agreement with API to Company No. 1, also subject to an exclusivity agreement?
A. Yes.
Q. Subject to this agreement, again, API Company No. 1 shall only manufacture and supply API exclusively to Fera, correct?
A. Yes.
MR. POLLACK: Justin, can you blow this up a little bit more, please, to get the whole provision and go down to 2.6. Thank you.
Q. Down here, it says, "During the term of the agreement, API No. 1 shall not cause its affiliates not to purchase, manufacture, supply or develop an alternate API, DMF and/or finished dosage form using the API in the territory, or (b) enter into any agreement with any third party to purchase, manufacture, supply or develop an alternate API, DMF and/or finished dosage form using the API for distribution in the territory."
Do you see that?
A. Yes.
Q. If we look at the agreement, "territory" is defined on page 2, in the fourth whereas clause, as the United States and its territories, correct?
A. Yes.

Q. In your written testimony, and just a few moments ago, you alluded to this, you stated that Fera requested exclusivity because of its investment in API 1's development process, right?

A. Yes.

Q. But Fera didn't seek to bar API Company No. 1 from selling pyrimethamine to third parties outside of the territory, correct?

A. Correct.

Q. So those third parties outside of the territory, they can benefit from the investment your company made in API Company No. 1's pyrimethamine manufacturing abilities, correct?

A. It would appear that way.

MR. POLLACK: One moment, your Honor?

(Pause)

MR. CASEY: Justin, will you please pull up GX 7015.

Q. Mr. Della Fera, using this document, are you able to tell me when API Company No. 1 was first able to manufacture pyrimethamine?

THE COURT: You can direct his attention to a specific line if you think that would be helpful to you, counsel.

MR. POLLACK: Thank you, your Honor.

Q. Mr. Della Fera, the only thing I see on here about the API is on May 28, 2019, Fera files pyrimethamine API DMF, on page 2 of the document.

Does that orient you to when API Company No. 1 first manufactured pyrimethamine?

MR. PERLMAN: Objection; this mischaracterizes the document.

THE COURT: Sustained.

MR. POLLACK: Did I misread the document?

A. Yes.

Q. My mistake.

May 28, 2019, Fera files pyrimethamine API DMF.

Does that orient you to when API Company No. 1 first manufactured pyrimethamine API?

A. Yes.

MR. PERLMAN: Same objection, your Honor.

THE COURT: So you want to use the reference to this filing to see if it refreshes his recollection as to when they first manufactured a batch of API?

MR. POLLACK: That's what I'm trying to do, your Honor.

THE COURT: Okay.

So, knowing the date of the filing, does that help you remember when they first succeeded in manufacturing a batch?

THE WITNESS: Yes, your Honor. What refreshed was the first page of this document.

Q. Oh, my mistake.

And what does the first page of the document tell you,

sir?

A. In October 2017 the initial batches were produced.

Q. Thank you, sir.

Between the time of contracting with API Company No. 1 and getting this initial batch, did your company ever reach out to another company with a European DMF called RL Fine?

A. I don't recall. I mean, we had a few people looking for the API, so...

Q. In fact, you did not, correct?

A. I don't recall.

MR. POLLACK: Justin, can we have his deposition at page 173, line 18 to 23.

Q. Mr. Della Fera, before I ask you about that, do you recall having your deposition taken on January 19, 2021?

A. I'm sorry, just --

Q. He just took it -- he'll put it back up, but do you remember having your deposition taken?

A. When was it? I'm sorry, Jeff.

Q. January 19, 2021.

A. Yes.

Q. And you were under oath there, as you are here?

A. Yes.

MR. POLLACK: Justin, can you put that back up, please.

Q. You testified: Okay, so you're not aware of any effort by

Fera to contact RL Fine about pyrimethamine API supply, and you said, no, I don't, I don't know any efforts personally, no.

A. I think my answer was the same. I said I don't recall. This is --

Q. You're the president of the company; is that right?

A. Yes.

Q. Were you involved in your company's efforts to manufacture Daraprim, generic Daraprim?

A. Yes.

Q. After API Company No. 1 manufactured its first batches of pyrimethamine API, did it file for a DMF?

A. I'm sorry, Jeff, can you repeat that?

Q. Yes. After API Company No. 1 manufactured its first batches of API, it filed for a DMF, correct?

A. No, we -- it takes months to prepare for a final for a DMF.

Q. I understand. But at some point after the manufacture, there was a filing for a DMF, correct?

A. It was in that other page that you referenced, in May of 2019.

Q. Am I correct that your company held the DMF?

A. No. We created the DMF; we didn't hold the DMF.

Q. Can you explain to us what that means, by creating the DMF?

A. Making those three batches is not a DMF. It's a huge document, and all the data has to be put together, and testing, and things of that nature. I think we initiated the work in

January of '18, a couple of months after we got the raw material, and it took over a year and three months to get it all done. That's why we prefer using material that's already approved or filed with the FDA.

Q. In 2020, did another generic --

A. But I want to add to that because you asked a good question.

I think when we got the material, on January 30, 2018, the two bottles of Daraprim, is when we went full speed, because it's an expensive process, building DMF and doing everything else around the project.

So you just helped me recollect. Thank you.

Q. When you said your company filed for the DMF, does that mean that you were the company of record for the DMF with the FDA?

A. Yes.

Q. And, in fact, in late 2020, were you contacted by another generic pharmaceutical company to purchase API?

A. Yes.

Q. Was that company Tanner Pharmaceuticals?

A. No.

Q. I'm sorry, was that company Teva Pharmaceuticals?

A. Yes.

Q. Thank you.

Do you know what price you quoted -- first of all, did

you quote a price to Teva?

A. Yes.

Q. Do you know what price you quoted?

A. We gave them a price that they wouldn't buy it.

Q. Why did you do that?

A. Because I don't want to deal with them.

Q. Are you aware that Teva's ANDA for generic Daraprim was approved in August of 2021?

A. Yes.

Q. Do you know who supplied Teva's API?

A. I can make a guess but I don't know a fact.

THE COURT: Is this a good place to stop, counsel?

MR. POLLACK: Yes, I'm about to change topics, your Honor.

THE COURT: Great. We will recess for the day. Just give me one second.

You may step down, sir. Thank you so much.

THE WITNESS: Thank you, your Honor.

Your Honor, what do I do with these documents?

THE COURT: You just leave them right there. Counsel are going to take care of them.

THE WITNESS: Terrific.

(Witness temporarily excused)

THE COURT: So, counsel, again, I'll check with my team and see if this is accurate, but I think the plaintiffs

have used six hours and one minute, and the defense counsel have used four hours and twenty-nine minutes, but I'll let you know tomorrow morning if that's wrong.

Let me ask counsel — and thank you very much for this notice of the next set of witnesses, beginning with Mr. Dorfman — are we on track, as far as you're concerned?

MR. MEIER: Your Honor, I think we are on track. It's going a little bit longer, but, as your Honor knows, there have been a few witnesses that have dropped out, so we were always a bit concerned of whether we were going to get a full Wednesday anyway, so I think with Ms. McDougal and Mr. Della Fera finishing, and Ms. McDougal, that we're going to be pretty much on track tomorrow.

THE COURT: Okay, good.

So you expect to get through these additional four witnesses tomorrow?

MR. MEIER: So I'm actually missing the email, I'm missing the email that we sent --

THE COURT: Dorfman, Mkhopadhyah, Hemphill and Conroy.

MR. MEIER: I don't think we'll get through Mr. Conroy, and we're hopeful we will get through Mr. Hemphill, or Professor Hemphill.

THE COURT: Okay. Everyone, have a nice evening. See you tomorrow morning.

(Adjourned to December 16, 2021 at 9:30 a.m.)

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DEFENDANT EXHIBITS